Calendar No. 97

109TH CONGRESS
1ST SESSION

S. 975

To provide incentives to increase research by private sector entities to develop medical countermeasures to prevent, detect, identify, contain, and treat illnesses, including those associated with a biological, chemical, nuclear, or radiological weapons attack or an infectious disease outbreak, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 29 (legislative day, APRIL 28), 2005

Mr. LIEBERMAN (for himself, Mr. HATCH, and Mr. BROWNBACK) introduced the following bill; which was read the first time

MAY 9, 2005

Read the second time and placed on the calendar

A BILL

To provide incentives to increase research by private sector entities to develop medical countermeasures to prevent, detect, identify, contain, and treat illnesses, including those associated with a biological, chemical, nuclear, or radiological weapons attack or an infectious disease outbreak, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

(a) SHORT TITLE.—This Act may be cited as the ''Project BioShield II Act of 2005''.

(b) IN HONOR.—This Act is enacted in honor of Robert Stevens, Thomas Morris, Jr., Joseph Curseen, Kathy Nguyen, Ottilie Lundgren, and Lisa J. Raines, victims of terrorist attacks in the United States in 2001.

(c) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—AMENDMENTS TO THE PROJECT BIOSHIELD ACT OF 2004 REGARDING TERROR COUNTERMEASURES

SEC. 101. PROCUREMENT OF CERTAIN DRUGS, DETECTION TECHNOLOGY, DIAGNOSTICS, AND RESEARCH TOOLS.

(a) IN GENERAL.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended—

(1) in section 319F–1(a)—

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively; and

(B) by inserting after paragraph (2) the following:

''(3) INCLUSION.—The term 'qualified countermeasure' includes detection technology, diagnostics, and research tools, as those terms are defined in section 319F–3.''; and

(2) in section 319F–2(c)(1)(B), in the matter preceding clause (i), by striking ''means a'' and inserting ''means detection technology, diagnostics, and research tools, as those terms are defined in 319F–3, a''.

(b) PURCHASE FUNDS.—Title V of the Homeland Security Act of 2002 (6 U.S.C. 311 et seq.) is amended by adding at the end the following:

"SEC. 512. COUNTERMEASURE PURCHASE FUND AT THE DEPARTMENT OF HOMELAND SECURITY.

"(a) PURCHASE FUND.—

"(1) ESTABLISHMENT OF FUND.—There is established in the Department a fund to be known as the 'Terrorism and Infectious Disease Countermeasure Purchase Fund' (referred to in this subsection as the 'Fund') consisting of amounts appropriated for expenditure by the Secretary under paragraph (4). This fund shall be separate from the special reserve fund established under section 510.

"(2) INVESTMENT OF FUND.—Amounts in the Fund shall be invested in accordance with section 9702 of title 31, United States Code, and any interest on, and proceeds from, any such investment shall be credited to and become part of the Fund.

"(3) USE OF FUND.—

"(A) IN GENERAL.—The Secretary shall expend amounts in the Fund—

"(i) for the purchase of countermeasures; and

"(ii) to provide advance, partial, progress or other payments, in accordance with subparagraph (E), to manufacturers of countermeasures.

"(B) PURCHASE.—Countermeasures shall be purchased by the Fund at the price and under the terms negotiated by the Secretary and the manufacturer or at a commercial price, if applicable.

"(C) COORDINATION WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The Secretary may delegate authority to the Secretary of Health and Human Services to purchase countermeasures using the Fund. Any such purchases by the Secretary of Health and Human Services shall be conducted as if made by the Secretary under this section.

"(D) CONDITIONS FOR PURCHASE.—

"(i) IN GENERAL.—Payments for purchases under subparagraph (A)(i) shall be made under such terms and conditions as are set forth in the contract between the parties.

"(ii) DETERMINATIONS.—The determinations required under section 319F–

2(c) of the Public Health Service Act shall not be required with respect to a contract, grant, or other transaction funded by the Fund under this section.

''(E) ADVANCE, PARTIAL, PROGRESS, OR OTHER PAYMENTS.—

''(i) IN GENERAL.—The Secretary may make payments under subparagraph (A)(ii) to manufacturers of countermeasures prior to the final purchase of such countermeasure.

''(ii) BASIS FOR PAYMENTS.—Payments under this subparagraph shall be based on—

''(I) the performance of the manufacturer involved as measured by the Secretary using objective, quantifiable methods (such as delivery of acceptable items, work measurement, or statistical process controls) established by the Secretary;

''(II) the accomplishment of events or milestones as defined in a program management plan that is de-

veloped by the manufacturer and submitted to the Secretary; or

"(III) other quantifiable measures of results determined appropriate by the Secretary.

"(iii) NUMBER, TIME, AND AMOUNT OF PAYMENTS.—

"(I) IN GENERAL.—The Secretary shall, with respect to a manufacturer of a countermeasure, determine the number of payments to be made, the timing of such payments, and subject to subclause (II), the amount of each such payment.

"(II) LIMITATION.—The amount of a partial payment made to a manufacturer under this subparagraph shall not exceed the portion of the total purchase price (described in subparagraph (B)) for the countermeasure that remains unpaid as of the date of the payment involved.

"(iv) CONDITIONS FOR PAYMENT.—The Secretary shall ensure that any payment to which this subparagraph applies is

commensurate with the actions taken by the manufacturer and the progress made in achieving the performance measures under clause (ii)(I) through the time of such payment. The manufacturer shall provide such information and evidence as such Secretary determines necessary to determine compliance with the preceding sentence.

''(v) INDEPENDENT RESEARCH AND DEVELOPMENT COSTS.—The payment amount under this subparagraph may include the costs associated with independent research and development undertaken by the manufacturer prior to entering into a contract or other agreement with the Secretary under this section.

''(4) AUTHORITY TO CONTRACT.—

''(A) IN GENERAL.—For purposes of a procurement under this subsection, the Secretary shall have responsibilities described in subparagraphs (B) and (C).

''(B) PROCUREMENT.—

''(i) IN GENERAL.—The Secretary shall be responsible for—

''(I) arranging for procurement of a countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into contracts, cooperative agreements, or other transactions, and for carrying out such other activities as may reasonably be required; and

''(II) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

''(ii) OTHER TRANSACTION AUTHORITY, ADDITIONAL AUTHORITY FOR RESEARCH PROJECTS.—The Secretary shall have the authority to enter into transactions (other than procurement contracts, grants, and cooperative agreements), including transactions for prototypes, to the same extent as provided to the Secretary of Defense under section 2371 of title 10, United States Code, for purposes of carrying out the objectives of the Project BioShield II Act of 2005.

''(iii) CONTRACT TERMS.—

"(I) MANDATORY TERMS.—A contract for procurement under this subsection shall include the following terms:

"(aa) CONTRACT DURATION.—The contract shall be for a period not to exceed 10 years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding a total of 18 years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such an extended period. The contract shall be renewable for additional periods, none of which shall exceed 5 years.

"(bb) PRODUCT APPROVAL.—The contract shall provide that the vendor seek approval, clearance, or licensing or validating of the product from the Secretary or other appropriate Federal agency and for a

timetable for the development of data and other information to support such approval, clearance, or licensing, and that the Secretary may waive part or all of such contract term on request of the vendor or on the initiative of the Secretary.

''(II) STORAGE BY VENDOR.—A contract for procurement under this subsection may provide that the vendor provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the purchase fund under subsection (a) shall be available for costs of shipping, handling, storage, and related costs for such product.

''(III) WARM INDUSTRIAL BASE FEE.—A contract for procurement under this section may provide that

the vendor receive a fee for establishing and maintaining manufacturing capacity in excess of the initial requirement of purchase of the countermeasure, in order to ensure that the Secretary has available a warm industrial base in the event of the need to increase purchases of countermeasures. To the extent practicable, the Secretary shall modify contracts in existence on the date of enactment of this Act to have available a warm industrial base. The cost of maintaining a warm industrial base shall be an allowable and allocable direct cost to the contract.

''(IV) PURCHASE OF FDA LICENSED PRODUCTS.—Nothing in this section shall be construed to prevent the Secretary from purchasing countermeasures that are licensed by the Food and Drug Administration for the indicated use or, in the event of a countermeasure that is established to be safe and effective for uses other

than those indicated on the label of such countermeasure, a use for which the vendor may be approved under emergency use authorities or approval by the Food and Drug Administration subsequent to purchase.

''(V) OTHER CONTRACT REQUIREMENTS.—

''(aa) COST ACCOUNTING STANDARD.—Notwithstanding any other provision of law, the cost accounting standards set forth under chapter 99 of title 48, Code of Federal Regulations, the cost principles set forth under part 31 of title 48, Code of Federal Regulations, and the requirement for submission of certified cost and pricing data under section 304A of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254b) shall not apply to any contract, grant, or cooperative agreement entered into under the

Project BioShield Act of 2004 (or the amendments made to such Act by the Project BioShield II Act of 2005.).

''(bb) SINGLE TRANSACTION.—The Secretary shall, to the extent practicable, enter into a single transaction with each contractor for the procurement of countermeasures, even if additional research and development of such countermeasures may be required, so long as the Secretary determines that sufficient and satisfactory clinical experience or research data supports a reasonable conclusion that such security countermeasures will qualify for approval or licensing by the Food and Drug Administration within 8 years from the date of entering into the procurement transaction.

''(iv) PROCUREMENT OF MULTIPLE PRODUCT AND TECHNOLOGIES.—Notwithstanding any other provision of law, the

Secretary shall, to the maximum extent practicable, enter into multiple transactions for the procurement of multiple technologies and products from multiple manufacturers of countermeasures in order to mitigate the risks associated with dependence on a single supplier or technology.

''(v) SINGLE TRANSACTION.—The Secretary shall, to the extent practicable, enter into a single transaction for the procurement of countermeasures, even if additional research and development of such countermeasures may be required, so long as the Secretary determines that sufficient and satisfactory clinical experience or research data supports a reasonable conclusion that such security countermeasures will qualify for approval or licensing by the Food and Drug Administration within 8 years from the date of entering into the procurement transaction. The fact that an entity has not filed for investigational new drug status with the Food and Drug Administration, or has filed for such status

but has not yet been approved, shall not be the sole basis for a determination by the Secretary with respect to whether a countermeasure qualifies for approval or licensing by the Food and Drug Administration not more than 8 years from the date of the procurement transaction.

''(vi) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

''(I) IN GENERAL.—If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

''(aa) section 303(g)(1)(A) of the Federal Property and Ad-

ministrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

"(bb) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

"(II) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subclause (I) and the provisions of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

"(aa) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

"(bb) Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57 (a) and (b)).

"(cc) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the examination of contractor records).

"(dd) Section 3131 of title 40, United States Code (relating to bonds of contractors of public buildings or works).

"(ee) Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a)) (relating to contingent fees to middlemen).

"(ff) Section 6002 of the Solid Waste Disposal Act (42 U.S.C. 6962).

"(gg) Section 1354 of title 31, United States Code (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

"(III) INTERNAL CONTROLS TO BE ESTABLISHED.—The Secretary shall establish appropriate internal controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

"(IV) AUTHORITY TO LIMIT COMPETITION.—In conducting a procurement under this subparagraph, the Secretary may not use the authority provided for under subclause (I) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield II Act of 2005 would be seriously impaired without such a limitation.

"(vii) PROCEDURES OTHER THAN FULL AND OPEN COMPETITION.—

"(I) IN GENERAL.—In using the authority provided in section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)) to use procedures other than competitive procedures in the case of a procurement under this subsection, the phrase 'available from only one responsible source' in such section 303(c)(1) shall be deemed to mean 'available from only one responsible source or only from a limited number of responsible sources'.

"(II) RELATION TO OTHER AUTHORITIES.—The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

"(III) APPLICABLE GOVERNMENT WIDE REGULATIONS.—The Secretary shall implement this clause in accordance with regulations implementing such section 303(c)(1) (including requirements that offers be solicited

from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

''(viii) PREMIUM PROVISION IN MULTIPLE AWARD CONTRACTS.—

''(I) IN GENERAL.—If, under this subsection, the Secretary enters into contracts with more than one vendor to procure a countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that identifies an increment of the total quantity of countermeasure required,

whether by percentage or by numbers of units.

''(II) DETERMINATION OF GOVERNMENT'S REQUIREMENT NOT REVIEWABLE.—If the Secretary includes in each of a set of contracts a provision as described in subclause (I), such Secretary's determination of the total quantity of countermeasures required, and any amendment of such determination, is committed to agency discretion.

''(ix) EXTENSION OF CLOSING DATE; RECEIPT OF PROPOSALS NOT REVIEWABLE.—A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

''(x) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 303A(a)(l)(B) of the Federal Prop-

erty and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B)) if such request has given notice that the Secretary may so exclude such a source.

''(C) COUNTERMEASURES PURCHASED.—Any stockpiles of countermeasures purchased under this section may be held in the strategic national stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b).

''(5) REQUIREMENTS FOR MANUFACTURERS.—The Secretary, or the Secretary of Health and Human Services under delegated authority, shall provide to manufacturers to the extent feasible the logistical and operational requirements of countermeasures prior to their development and acquisition. The logistical and operational requirements will consider public health needs as well as requirements for storage, maintenance, security, rotation, and transport of any countermeasures purchased through the Countermeasure Purchase Fund.

''(6) COORDINATION.—Consistent with the provisions of section 319F–2(c)(2)(B) of the Public Health Service Act, the Secretary shall coordinate with the Secretary of Health and Human Services to

store, maintain, secure, rotate, and transport any materiel purchased through the Countermeasure Purchase Fund and designated for use in the Strategic National Stockpile under such section 319F–2.

''(7) APPROPRIATION.—

''(A) IN GENERAL.—The total appropriations made available for both the Fund under section 512 and the special reserve fund under section 510 may be used to provide funding for activities conducted by the Secretary and, where appropriate, the Secretary of Health and Human Services, in accordance with the Project BioShield Act of 2004 and the Project BioShield II Act of 2005 (and the amendments made by such Acts).

''(B) USE OF FUNDS.—The Secretary, or the Secretary of Health and Human Services under delegated authority, may use the funds under this section to cover the costs of storage, maintenance, security, rotation, and transport of any material purchased through the Countermeasure Purchase Fund.''.

''(b) DEFINITION.—In this section, the term 'countermeasure' has the meaning given such term in section 319F–3 of the Public Health Service Act.''.

SEC. 102. ADDITIONAL AUTHORITY UNDER PROJECT BIOSHIELD.

(a) ADDITIONAL AUTHORITY FOR RESEARCH PROJECTS.—Section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a) is amended by—

(1) redesignating subsection (f) as subsection (g); and

(2) inserting after subsection (e) the following:

''(f) OTHER TRANSACTION AUTHORITY.—The Secretary shall have the authority to enter into transactions (other than procurement contracts, grants, and cooperative agreements), including transactions for prototypes, to the same extent as provided to the Secretary of Defense under section 2371 of title 10, United States Code, for purposes of carrying out the objectives of the Project BioShield Act of 2004.''.

(b) ENCOURAGEMENT OF TECHNOLOGY TRANSFER AND COMMERCIALIZATION.—Section 319F–2(c)(5)(B)(iii) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(5)(B)(iii)) is amended to read as follows:

''(iii) Where there is a potential to transfer the technology developed as a security countermeasure to the commercial market, either as a countermeasure to be sold in foreign markets or, if the countermeasure has beneficial use and utility for

indications other than chemical, biological, radiological, or nuclear protection, for use as other than a countermeasure in commercial markets thus meriting Federal funding to stimulate and encourage such commercialization and technology transfer, and demonstrating a potential return on such Federal investment.''.

(c) PROCUREMENT OF CERTAIN COUNTERMEASURES.—Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended by—

(1) redesignating subsections (e) and (f) as subsections (l) and (m), respectively; and

(2) by inserting after subsection (d) the following:

''(e) PROCUREMENT OF CERTAIN COUNTERMEASURES.—

''(1) IN GENERAL.—The Secretary shall, to the extent practicable, enter into transactions for the procurement of security countermeasures, even if additional research and development of such security countermeasures may be required, so long as the Secretary determines that sufficient and satisfactory clinical experience or research data supports a reasonable conclusion that such security counter-

measures will qualify for approval or licensing by the Food and Drug Administration within 8 years from the date of entering into the procurement transaction.

''(2) BASIS FOR DETERMINATION.—The fact that an entity has not filed for Investigational New Drug status with the Food and Drug Administration, or has filed for such status but has not yet been approved, shall not be the sole basis for a determination by the Secretary with respect to whether a security countermeasure qualifies for approval or licensing by the Food and Drug Administration within 8 years from the date of entering into the procurement transaction.

''(f) EFFECT OF SECTION.—Notwithstanding any other provision of law, the cost accounting standards set forth under chapter 99 of title 48, Code of Federal Regulations, the cost principles set forth under part 31 of title 48, Code of Federal Regulations, and the requirement of the submission of certified cost and pricing information under section 254b of title 41, United States Code, shall not apply to any contract, grant, or cooperative agreement entered into under the Project BioShield Act of 2004 (or the amendments made to such Act by the Project BioShield II Act of 2005).

''(g) ACCELERATED APPROVAL.—An entity that enters into an agreement under this section, section 319F–1, or section 512 of the Homeland Security Act of 2002 shall be eligible for accelerated approval of a countermeasure in accordance with section 573 of the Federal Food, Drug, and Cosmetic Act.

''(h) PROCUREMENT OF MULTIPLE PRODUCT AND TECHNOLOGIES.—Notwithstanding any other provision of law, the Secretary shall, to the extent practicable, enter into multiple transactions for the procurement of multiple technologies and products from multiple manufacturers of qualified and security countermeasures (as defined by this section and section 319F–1) in order to mitigate the risks associated with dependence on a single supplier or technology.

''(i) WARM INDUSTRIAL BASE FEE.—A contract for procurement under this section may provide that the vendor receive a fee for establishing and maintaining manufacturing capacity in excess of the initial requirement of purchase of the countermeasure, in order to ensure that the Secretary has available a warm industrial base in the event of the need to increase purchases of countermeasures. To the extent practicable, the Secretary shall modify contracts in existence on the date of enactment of this subsection to have available a warm industrial base.

The Secretary shall deem the cost of such fee allowable and allocable as a direct cost to the contract.

''(j) PURCHASE OF FDA LICENSED PRODUCTS.—Nothing in this section shall be construed to prevent the Secretary from purchasing countermeasures that are licensed by the Food and Drug Administration for the indicated use or, in the event of a countermeasure that is established to be safe and effective for uses other than those indicated on the label of such countermeasure, a use for which the vendor may be approved under emergency use authorities or approval by the Food and Drug Administration subsequent to purchase.''.

(d) TECHNICAL AMENDMENTS.—Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended by—

(1) in the section heading, inserting ''and Security Countermeasure Procurements'' after ''Stockpile''; and

(2) in subsection (c)—

(A) in the heading, by deleting ''biomedical'';

(B) in paragraph (5)—

(i) by amending subparagraph (A) to read as follows:

''(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) or acquisition for other purposes pursuant to procurements made with amounts in the special reserve fund under paragraph (10) (referred to in this subsection individually as a ''procurement under this subsection'').'';

and

(ii) in subparagraph (B)(ii), by deleting the word ''stockpile'' and inserting ''government'';

(C) by amending paragraph (6)(D) to read as follows:

''(D) Subsequent specific countermeasures.—Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate

for inclusion in the stockpile or acquisition for other purposes and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.''; and

(D) in paragraph (8)—

(i) in subparagraph (A)—

(I) by striking ''COOPERATION.—'' and all that follows through ''out'' and inserting ''COOPERATION.—In carrying out''; and

(II) by striking '', subject to subparagraph (B),''; and

(ii) by striking subparagraph (B).

SEC. 103. REQUEST OF AGENCY.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) (as amended by section 102) is further amended by inserting after subsection (j) the following:

''(k) REQUEST OF AGENCY TO USE BIOSHIELD I AND BIOSHIELD II AUTHORITY AND INCENTIVES.—

''(1) IN GENERAL.—Upon request by a Federal agency, the Secretary may establish interagency agreements, under terms acceptable to the Secretary, in which such agency may order countermeasures under procurement contracts or procurement pools established by the Secretary.

''(2) PROCESSING OF ORDERS.—The ordering of a countermeasure under an agreement under paragraph (1) (including transfers of appropriated funds between an agency and the Department to pay for such orders) may be conducted pursuant to section 1535 of title 31, United States Code, if such order is processed under the terms established—

''(A)(1) in the interagency agreement required by subsection (c)(7)(B), for orders of detection technology and decontamination technology placed by the Department of Homeland Security; or

''(2) by the Secretary in the interagency agreement described under paragraph (1) for all other orders; and

''(B) in the Project BioShield Act of 2004 and the Project BioShield II Act of 2005 (and the amendments made by such Acts) with re-

spect to the procurement of countermeasures under this section and section 319F–1.''.

TITLE II—AMENDMENTS TO THE PROJECT BIOSHIELD ACT OF 2004 REGARDING INFECTIOUS DISEASE COUNTERMEASURES; ADDITIONAL PROVISIONS

SEC. 201. AMENDMENTS TO THE PROJECT BIOSHIELD ACT OF 2004 REGARDING INFECTIOUS DISEASE COUNTERMEASURES.

(a) COUNTERMEASURES TO DETECT, DIAGNOSE, PREVENT, OR TREAT AN INFECTIOUS DISEASE.—

(1) PROCUREMENT AUTHORITY.—Section 319F–1(a)(2) of the Public Health Service Act (42 U.S.C. 247d–6a) is amended—

(A) in subparagraph (A), by striking ''; or'' and inserting a semicolon;

(B) in subparagraph (B), by striking the period and inserting ''; or''; and

(C) by adding after subparagraph (B) the following:

''(C) detect, diagnose, treat, or prevent an infectious disease (as defined in section 319F–3(a)(6)) adversely affecting public health.''.

(2) STRATEGIC NATIONAL STOCKPILE.—Section 319F–2(c)(1)(B) of the Public Health Service Act is amended—

(A) in clause (i)(III)(bb), by striking ''; or'' and inserting a semicolon;

(B) in clause (ii), by striking the period and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) is intended to detect, diagnose, prevent, or treat an infectious disease (as defined in section 319–3(a)(6)).''.

SEC. 202. PROCUREMENT POOLS; ADDITIONAL INCENTIVES UNDER PROJECT BIOSHIELD.

(a) IN GENERAL.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.), as amended by section 101, is amended by inserting after section 319F–2 the following:

''SEC. 319F–3. PROCUREMENT OF CERTAIN DRUGS, DETECTION TECHNOLOGY, DIAGNOSTICS, AND RESEARCH TOOLS.

''(a) DEFINITIONS.—For purposes of this part:

''(1) BIOLOGICAL OR CHEMICAL AGENT; TOXIN; NUCLEAR OR RADIOLOGICAL MATERIAL; TERROR WEAPON.—The term—

"(A) 'biological agent', 'biological toxin', or 'chemical agent', or any variation of any such term, includes any microorganism, virus, infectious substance, toxic biological product, or toxic or poisonous chemical, that may be used in a manner that may cause widespread death or serious bodily injury, including biological agents and toxins described in paragraphs (1) and (2) of section 178 of title 18, United States Code;

"(B) 'nuclear or radiological material' means any radioactive material that may be used in a manner that may cause widespread death or serious bodily injury; and

"(C) 'terror weapon' or 'weapon of mass destruction' mean any matter described in subparagraph (A) or (B) that may be used in a manner that may cause widespread death or serious bodily injury.

"(2) COUNTERMEASURE.—The term 'countermeasure' means—

"(A) a vaccine and related delivery system, anti-infective, antibiotic or combinations thereof, therapy, microbicide, diagnostic technology, drug, biological product, chemical, or other

technology that is subject to applicable provisions of this Act, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.), and that prevents infection with, or the spread of, or the directly diagnose, treat, or prevent the pathological effects of infection with, bodily harm from, or the spread of, a biological or chemical agent or toxin on the list described in subsection (f), including treatments for addressing excessive bleeding and other trauma following a terrorist attack;

''(B) a therapy, diagnostic, or piece of equipment that may be used to detect, treat, or prevent bodily harm that may be caused by the use of biological, chemical, nuclear, or radiological material as a terror weapon or by an infectious disease;

''(C) a qualified countermeasure, as defined in section 319F–1; or

''(D) a security countermeasure, as defined in section 319F–2.

''(3) DECONTAMINATION TECHNOLOGY.—The term 'decontamination technology' means a product

or service used for the decontamination of property following a terrorist attack.

''(4) DETECTION TECHNOLOGY.—The term 'detection technology' means scientific instruments, consumables (such as reagents or assays, including reagents or assays using polymerase chain reaction (PCR) or Real Time PCR), software, or services for the detection of the presence, concentration, characteristics, or identification of a biological, chemical, nuclear, radiological agent, or infectious disease in environmental or field samples.

''(5) DEVELOPMENT.—The term 'development' or 'to develop' includes research leading to the identification and isolation of suitable compounds or biological materials, the engineering, modification (including research leading to the expanded use of currently approved drugs or biological products), evaluation, production, and formulation of such compounds or materials, the conduct of preclinical and clinical studies, the preparation of an application for marketing approval, and preparation of test methods, with respect to countermeasures regulated by the Food and Drug Administration, and other actions prior to approval of a countermeasure by the Food and Drug Administration or when it is pro-

cured as an unlicensed countermeasure under section 319F–2(e).

''(6) DIAGNOSTICS.—

''(A) IN GENERAL.—The term 'diagnostics' includes products, devices, and technologies to detect, identify, or analyze the potential presence of, or exposure to, 1 or more biological, nuclear, radiological, or chemical agent or toxin in potentially exposed individuals through means to enable effective medical intervention through the administration of appropriate countermeasures.

''(B) INCLUSION.—The term 'diagnostics' includes technologies that diagnose or screen for the health and safety of potentially exposed individuals and products that serve as contraindicators for vaccines or drugs.

''(7) INFECTIOUS DISEASE.—

''(A) IN GENERAL.—The term 'infectious disease' means a disease in humans caused by—

''(i) a microbe (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person;

''(ii) microbial products (such as botulinum toxin); or

''(iii) a prion.

''(B) INCLUSION.—The term 'infectious disease' includes—

''(i) a disease in humans caused by a microorganism, whether or not—

''(I) such microorganism is acquired by an individual through human-to-human contact; or

''(II) if the individual is initially symptomatic of the disease; and

''(ii) zoonotic diseases that may find hosts in animal and human populations.

''(8) MANUFACTURER.—

''(A) IN GENERAL.—The term 'manufacturer' means an entity responsible for research, evaluation, development, or production of a countermeasure and, except for a countermeasure that is not subject to review and approval by the Food and Drug Administration prior to marketing (such as research tools), the potential or actual holder of the approved new drug application, biologic license application, or

product license application or equivalent for such countermeasure.

"(B) LIMITATION.—The term 'manufacturer' does not require that a manufacturer conduct the actual research, evaluation, development, or production in its own facilities, but may enter into arrangements with third parties for the research, evaluation, development, or production of the countermeasure.

"(9) RESEARCH TOOL.—The term 'research tool' includes the full range of tools and systems that accelerate the discovery, development, and manufacture of countermeasures, including animal disease models, cell lines, cell line cultures for the production of biologics, de novo DNA synthesis, monoclonal and polyclonal antibodies, reagents or assays (such as those utilizing the polymerase chain reaction (PCR) or Real Time PCR processes), drug delivery technologies, vaccine adjuvants, antibiotic sensitivity screens, laboratory animals, large animals including nonhuman primates (and other such animals used or intended to be used for drug production), growth factors, combinatorial chemistry and DNA libraries, vaccine antigen libraries, clones and cloning tools (such as PCR or Real Time PCR),

methods, laboratory equipment and machines, databases, and other technologies that enable the rapid and effective development of countermeasures, including diagnostics, vaccines, drugs, antibiotics, nonlaboratory tools, and tools systems that directly assist such countermeasure development efforts.

''(b) PROCUREMENT POOLS.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall establish, and make payments from, procurement pools with respect to the procurement of a qualified countermeasure under section 319F–1 or a security countermeasure under section 319F–2.

''(2) ROLE OF OTHER ORGANIZATIONS.—In organizing the procurement pools under paragraph (1), the Secretary may accept contributions and guarantees from—

''(A) non-governmental organizations;

''(B) international health agencies;

''(C) the United Nations;

''(D) the Global Vaccine Acquisition Initiative; and

''(E) private nonprofit organizations that are organized to support international public health research and programs.

''(3) CONSULTATION.—The Secretary shall—

''(A) consult with the organizations described under paragraph (2) regarding the terms and management of procurement contracts that exceed $25,000,000 in value under this section and sections 319F–1 and 319F–2 that receive payment from the procurement pool established under paragraph (1); and

''(B) provide information to such organizations regarding such procurement contracts.

''(4) LIMITATION.—Nothing in this part shall be construed to prohibit the Secretary or the Secretary of Homeland Security (with respect to procurement agreements under section 512 of the Homeland Security Act of 2002) from accepting contributions and guarantees from organizations that receive funding from the Federal Government.

''(5) CONTRIBUTION TO OTHER POOLS.—The Secretary and the Secretary of Homeland Security (with respect to procurement agreements under section 512 of the Homeland Security Act of 2002) may contribute funds to procurement pools organized by other entities, such as foreign governments, the United Nations, or nonprofit or non-govern-

mental entities for procurement of qualified and security countermeasures.

''(c) ADVISORY COMMITTEE.—

''(1) ESTABLISHMENT.—The Secretary shall establish an advisory committee to be known as the International Public Health Advisory Committee (referred to in this section as the 'Advisory Committee').

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—The Advisory Committee shall be composed of representatives, to be appointed by the Secretary, from organizations, including the Centers for Disease Control and Prevention and the organizations described in subparagraph (B), with expertise and resources regarding the development and distribution of countermeasures against biological, chemical, nuclear, or radiological agents or infectious diseases.

''(B) ORGANIZATIONS DESCRIBED.—The organizations described under this subparagraph are—

''(i) non-governmental organizations;

''(ii) international health agencies;

''(iii) the United Nations;

"(iv) the Global Vaccine Acquisition Initiative; and

"(v) private nonprofit organizations that are organized to support international public health research and programs.

"(3) DUTIES OF ADVISORY COMMITTEE.—The Advisory Committee, through a public process, shall—

"(A) develop an international, multifaceted, and coordinated strategy, that, with respect to countermeasures against biological, chemical, radiological, and nuclear agents or infectious disease—

"(i) develops strategies for establishing procurement pools;

"(ii) develops strategies to facilitate partnerships between the government and private sector;

"(iii) makes recommendations for strengthening the infrastructure necessary for researching, creating, and stockpiling critical therapeutics;

"(iv) recommends ways in which the countermeasure development process may be shortened; and

''(v) makes recommendations for priority areas for developing research and discovery programs necessary to develop countermeasures;

''(B) develop criteria for determining which countermeasures against biological, chemical, nuclear, and radiological agents or infectious disease should be developed and procured;

''(C) explore priority broad spectrum therapeutics and ways in which the countermeasure development process may be accelerated to facilitate rapid development of new drugs in the event of an attack with a previously unknown biological agent or pathogen; and

''(D) recognize the importance and the need for advancement in the field of bioinformatics which will accelerate the discovery or development of all types of countermeasures by promoting the use of advanced mathematical, computing, or image processing technologies, including pattern recognition methods, lossless digital data compression for storage and transmission of biomedical images, and the ability to analyze massive amounts of

data, in order to solve complex research and development problems.

''(d) DIAGNOSTICS INCENTIVES.—

''(1) IDENTIFICATION.—Not later than 180 days after the date of enactment of the Project BioShield II Act of 2005, the Secretary shall develop and make available to potential manufacturers, a list of the diagnostics that need to be developed to prepare the United States for a terrorist attack using a biological or chemical agent, infectious disease, toxin, or nuclear or radiological materials, or to counter a naturally occurring infectious disease outbreak. The Secretary shall provide such information as the Secretary determines to be necessary to enable such potential manufacturers to structure and focus their research and development programs for the development of such research tools.

''(2) REVISIONS.—The Secretary shall revise the list developed under paragraph (1) not less often than annually, and make such list available to potential manufacturers of diagnostics under terms and conditions consistent with the security interests of the United States.

''(3) DEVELOPMENT OF CERTAIN DIAGNOSTICS.—

"(A) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Public Health Countermeasure Development, shall develop and implement, in consultation with State and local public health officials and private sector entities, a strategy for the development of infectious disease multiplexed molecular level diagnostic screening technologies and the building of an integrated and standardized information system linking the Federal, State, and local public health systems for reporting automated laboratory results for all toxicology and infectious diseases. The strategy shall address the integration, correlation, and analysis from laboratory results with data generated from environmental monitoring using detection technology.

"(B) STRATEGY.—The strategy developed and implemented pursuant to subparagraph (A) shall—

"(i) include the development of confirmatory laboratory tests to validate presumptive results available from initial screening;

"(ii) complement the development of therapeutics where appropriate; and

"(iii) promote the advancement of bioinformatics through the use of incentives, the procurement and rapid development of new devices, and the development of a robust and standardized information infrastructure for carrying out medical surveillance tasks.

"(C) TECHNOLOGY.—

"(i) IN GENERAL.—The specific screening and diagnostics technology used to implement the strategy described in subparagraph (A) may consist of multiplexed devices that screen for routinely encountered common infectious diseases and have biothreat agent detection algorithms embedded in the devices with automatic reporting features.

"(ii) DISSEMINATION AND EVALUATION.—The Secretary shall develop—

"(I) the methods by which the results from such detection devices may be rapidly disseminated to the appro-

priate domestic and international health care systems; and

"(II) a system by which the utility of such results, and the efficacy of such dissemination system, may be evaluated and improved, as necessary.

"(4) UTILIZATION OF DIAGNOSTICS BY HEALTH CARE PROVIDERS.—

"(A) IN GENERAL.—The Secretary shall develop and implement a strategy that recognizes the need to provide the right incentives to the health care industry, including the qualified clinical countermeasures delivery centers under the Project Bioshield II Act of 2005, to allow the industry to utilize the new diagnostic tools that will be made available through research and allow for screening for infectious diseases and other biological, chemical, nuclear, radiological, and emerging terrorist threats.

"(B) REIMBURSEMENT.—The strategy shall include appropriate incentives to allow for reimbursement to State and local governments, hospitals, clinics, and other providers who perform laboratory screening utilizing newer molecular level tests that rapidly detect infectious

diseases and other biological, chemical, nuclear, radiological, and emerging terrorist threats.

''(C) STRATEGIES.—The Secretary shall establish similar strategies for States and local governments to utilize to promote biological, chemical, nuclear, radiological, and other emerging terrorist threats and infectious diseases screening, including testing for the rapid identification of potential biothreat agents.

''(5) NO JUDICIAL REVIEW.—Notwithstanding any other provision of law, there shall be no judicial review of the list, or revised list, developed by the Secretary under this subsection.

''(e) RESEARCH TOOLS INCENTIVES.—

''(1) IDENTIFICATION.—Not later than 180 days after the date of enactment of the Project BioShield II Act of 2005, the Secretary shall develop and make available to potential entities and manufacturers, a list of the research tools and the systems to aid in the development of such tools that need to be developed to prepare the United States for a terrorist attack, with a biological or chemical agent or toxin or nuclear or radiological materials, or to counter a naturally occurring infectious disease outbreak. The list developed by the Secretary shall

include research tools for which there is a need for development in order to understand why certain countermeasures may cause adverse events, how to minimize such adverse events, and how to treat such adverse events. The Secretary shall provide such information as the Secretary determines to be necessary to enable such potential manufacturers to structure and focus their research and development programs for the development of research tools.

''(2) REVISIONS.—The Secretary shall revise the list developed under paragraph (1) not less often than annually, and make such list available to potential manufacturers of research tools under terms and conditions consistent with the security interests of the United States.

''(3) NO JUDICIAL REVIEW.—Notwithstanding any other provision of law, there shall be no judicial review of the list, or revised list, developed by the Secretary under this subsection.

''(4) UTILIZATION AND AVAILABILITY.—

''(A) IN GENERAL.—Entities that enter into a contract for procurement of a qualified countermeasure under section 319F–1 or of a security countermeasure under section 319F–2, or under section 512 of the Homeland Security

Act of 2002 shall maximize the utilization of the research tools involved for the development of countermeasures. In addition, such entities shall promote the advancement of bioinformatics through the use of incentives for the development and procurement of bioinformatics research tools.

''(B) RULE OF CONSTRUCTION.—Nothing in this section or chapter 18 of title 35, United States Code, shall be construed to restrict the right of an entity described in subparagraph (A) to—

''(i) secure and enforce patents with regard to research tools;

''(ii) enter into exclusive, revocable, and nontransferable licenses of such research tools; or

''(iii) impose limits on royalty- or product-reach-through or downstream rights or agreements on future countermeasures or products, or option rights with respect to a research tool.

''(f) INITIAL LIST.—Not later than 180 days after the date of enactment of the Project BioShield II Act of 2005, the Secretary, in consultation with the Secretary of

Defense and the Secretary of Homeland Security, shall develop, publish in the Federal Register, and make available to potential manufacturers of terror weapons and infectious disease countermeasures, except as provided in subsection (i), a list of biological and chemical agents, toxins, and nuclear and radiological materials that may be used as weapons of mass destruction or that are infectious diseases with respect the which the Secretary finds that research to develop new and improved countermeasures is in the national interest of the United States. Such initial list may, at the discretion of the Secretary, contain the following:

''(1) Variola major (confluent, flat, and hemorrhagic smallpox).

''(2) Bacillus anthracis (anthrax) or near-neighbor pathogenic Bacillus spp.

''(3) Clostridium botulinum (botulism) or botulism toxins.

''(4) Francisella tularensis (tularemia).

''(5) Yersina pestis (Black Death: bubonic plague, pneumonic plague).

''(6) Pathogenic Haemophilus spp.

''(7) Ebolavirus spp. (Ebola hemorrhagic fever).

''(8) Marburgvirus spp. (Marburg hemorrhagic fever).

''(9) Arenavirus Lassa Virus (Lassa fever).

''(10) Arenavirus Junin Virus (Argentine hemmorrhagic fever).

''(11) Nairovirus Crimean-Congo hemorrhagic fever virus (Crimean-Congo hemmorrhagic fever).

''(12) Coxiella burnetti (Q fever).

''(13) Coccidioidomycosis immitis (Coccidioidomycosis, San Joaquin Valley, or desert fever).

''(14) Clostridium perfringens (gas gangrene, necrotizing enteritis).

''(15) Treponema spp.

''(16) Borrelia spp.

''(17) Chlamydia psittaci (parrot fever).

''(18) Phlebovirus Rift Valley fever virus (Rift Valley fever).

''(19) Rickettsia rickettsii (Rocky Mountain Spotted Fever).

''(20) Brucella spp. (brucellosis).

''(21) Burkholderia mallei (glanders).

''(22) Alphavirus Venezuelan equine encephalitis virus (Venezuelan equine encephalomyelitis).

''(23) Alphavirus Eastern equine encephalitis virus (Eastern equine encephalomyelitis) and Alphavirus Western equine encephalitis virus (Western equine encephalomyelitis).

''(24) Ricin toxin (castor bean toxin).

''(25) Trichothecene Mycotoxins.

''(26) Dinoflagellate neurotoxin (Paralytic Shellfish Toxin).

''(27) Aflatoxins.

''(28) Epsilon toxin of clostridium perfringens.

''(29) Staphylococcus enterotoxin B (Staphylococcus entertoxin B intoxication).

''(30) Methicillin-resistant staphylococcus aureus.

''(31) Influenza.

''(32) Avian influenza.

''(33) Pathogenic Salmonella spp. (gastrointestinal upset, enteric fever).

''(34) Salmonella Typhi (typhoid fever).

''(35) Shigella dysenteriae (dysentery, hemolytic-uremic syndrome).

''(36) Escherichia coli 0157:H7 (severe diarrhea, hemolytic-uremic syndrome) and other Escherichia coli pathotypes.

''(37) Vibrio species (cholera).

''(38) Toxoplasma gondii.

''(39) Cryptosporidium parvum.

''(40) Henipavirus Nipah virus (Nipa encephalitis).

''(41) Hantavirus spp. (Hantavirus Pulmonary Syndrome).

''(42) Tickborne hemorrhagic fever viruses.

''(43) Tickborne encephalitis virus.

''(44) Flavivirus Yellow Fever virus (Yellow fever, West Nile virus, Dengue).

''(45) Human Immunodeficiency Virus (HIV), Acquired Immune Deficiency Syndrome (AIDS)

''(46) Plasmodium falciparum, P. ovale, P. vivax, P. malariae (Malaria).

''(47) Rickettsia typhi (typhus).

''(48) Antibiotic-resistant Mycobacterium tuberculosis.

''(49) Entamoeba histolytica (amebiasis).

''(50) Pathogenic Shigella spp. (bacillary dysentery, Shigellosis).

''(51) Giardia lamblia (giardiasis).

''(52) Orthopox virus spp. (monkey pox infection).

''(53) Trypanosoma brucei gambiense or rhodesiense (trypanosomiasis, sleeping sickness).

''(54) Leishmania donovane (visceral leishmaniasis, black fever, Kala Azar).

''(55) Schistosoma mansoni, S. haematobium, S. japonicum (schistosomiasis or bilharzia).

''(56) Necator Americanus and Ancylostoma duodenale (hookworm).

''(57) Ascaris lumbricoides (roundworm).

''(58) Trichuris trichiura (whipworm).

''(59) Onchocerca volvulus (river blindness).

''(60) Drancunculus medianensis (guinea worm).

''(61) Wuchereria bancrofti and Brugia malayi (lymphatic filariasis or elephantiasis).

''(62) Mycobacterium ulcerans (Burulu Ulcer).

''(63) Mycobacterium leprea (leprosy).

''(64) Chlamydia trachomitis (Trachoma).

''(65) Pathogenic Streptococcus spp.

''(66) Nerve agents (including Tabun, Sarin, Soman, GF, VX, V-gas, third generation nerve agents organophosphate pesticides add carbamate insecticides).

''(67) Blood agents (including hydrogen cyanide and cyanogen chloride).

''(68) Blister agents (including Lewisite, nitrogen and sulfur mustards).

''(69) Heavy metals (including arsenic, lead, and mercury).

''(70) Volatile toxins (including benzene, chloroform, and trihalomethanes).

''(71) Pulmonary agents (including phosgene and chlorine vinyl chloride).

''(72) Incapacitating agents (including BZ).

''(73) Nuclear and radiological materials.

''(74) Exotic agents including hybrid organisms, genetically modified organisms, antibiotic-induced toxins, autoimmune peptides, immune mimicry agents, binary bioweapons, stealth viruses, and bioregulators and biomodulators.

''(75) Innovative treatments and measures to address trauma, including excessive bleeding, resulting from an act of terrorism.

''(76) Any other new and emerging natural infectious disease threats.

''(g) REVISIONS.—The Secretary shall revise the list developed under subsection (f) on at least an annual basis, and make such list available, under the terms and limitations described in this section, to potential manufacturers of terror weapons countermeasures, infectious disease countermeasures, or weapons of mass destruction countermeasures, or to holders of approved certifications. Such terms and conditions shall be consistent with the security interests of the United States.

''(h) NO JUDICIAL REVIEW.—Notwithstanding any other provision of law, there shall be no judicial review

of the Secretary's determinations regarding which agents, toxins, or materials to include on the list, or revised list, developed under this section or of a determination to exempt information from public distribution under this section.

''(i) EXEMPTION.—

''(1) IN GENERAL.—The Secretary may exempt certain information concerning weapons of mass destruction from publication if the Secretary determines that such publication would be detrimental to the security of the United States. In providing an exemption under the preceding sentence, the Secretary shall develop procedures for making such list or information available on a confidential basis to potential manufacturers of countermeasures.

''(2) SUFFICIENCY OF INFORMATION.—In developing the procedures described in paragraph (1), the Secretary shall ensure that the information provided to potential manufacturers of countermeasures is sufficient to enable the Federal Government and the manufacturer to determine when such a manufacturer has successfully developed a countermeasure and therefore becomes entitled to the procurement, intellectual property, and liability provisions of title

III of the Project BioShield II Act of 2005 (and the amendments made by such title).''.

(b) DETECTION TECHNOLOGY INCENTIVES.—Section 512 of the Homeland Security Act of 2002 (as added by section 101), is amended by—

(1) redesignating subsection (b) as subsection (d); and

(2) inserting after subsection (a) the following:

''(b) DETECTORS TECHNOLOGY INCENTIVES.—

''(1) IDENTIFICATION.—

''(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Project BioShield II Act of 2005, the Secretary shall develop and make available to potential manufacturers, a list of the infectious disease, biological, chemical, radiological, or nuclear agents to be detected as well as the name and seller of the detection technology furnished to the Government and whether the Secretary has certified such detection technology under section 301(b)(4) of the Project BioShield II Act of 2005. The detection targets shall include chemical or biological agents or toxins or nuclear or radiological materials.

''(B) AVAILABILITY OF INFORMATION.—The Secretary shall provide such information as the Secretary determines to be necessary to enable the potential manufacturers of terror weapons and infectious disease detection technology to structure and focus their research and development programs for the development of such technology.

''(C) REVISIONS.—The Secretary shall revise the list developed under subparagraph (A) not less often than annually, and make such list available to potential manufacturers of terror weapons and infectious disease detections equipment under terms and conditions consistent with the security interests of the United States.

''(D) NO JUDICIAL REVIEW.—Notwithstanding any other provision of law, there shall be no judicial review of the determinations by the Secretary regarding which agents, toxins, or materials are to be included on the list, or revised list, developed under this subsection.

''(E) CONSULTATION.—In developing and revising the list described under subparagraph (A), the Secretary shall consult with the Sec-

retary of Health and Human Services and the Secretary of Defense.

''(F) EXEMPTION.—

''(i) IN GENERAL.—The Secretary may exempt certain information concerning weapons of mass destruction from publication under this subsection if the Secretary determines that such publication would be detrimental to the security of the United States. In providing an exemption under the preceding sentence, the Secretary shall develop procedures for making such list or information available on a confidential basis to potential manufacturers of countermeasures.

''(ii) SUFFICIENCY OF INFORMATION.—In developing the procedures described in clause (i), the Secretary shall ensure that the information provided to potential manufacturers of countermeasures is sufficient to enable the Federal Government and the manufacturer to determine when such a manufacturer has successfully developed a countermeasure and therefore becomes entitled to the procurement, intel-

lectual property, and liability provisions of title III of the Project BioShield II Act of 2005 (and the amendments made by such title).

''(2) OTHER DETECTION TECHNOLOGY INCENTIVES.—

''(A) IN GENERAL.—In furnishing the list to potential vendors of detection technology, the Secretary shall promote the advancement of bioinformatics through the use of incentives for bioinformatics research tools to develop detection technology.

''(B) COOPERATION.—The Secretary shall cooperate with the Secretary of the Department of Homeland Security and in consultation with the appropriate Advisory Committees, in the course of DHS certification of detection technology countermeasures, to generate performance measures or performance standards (such as 'time to result', 'sensitivity', or 'specificity' with respect to a target pathogen) for such detection technology countermeasures.

''(c) DECONTAMINATION TECHNOLOGY INCENTIVES.—

''(1) IDENTIFICATION.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Project BioShield II Act of 2005, the Secretary shall develop and make available to potential manufacturers, a list of the infectious disease, biological, chemical, radiological, or nuclear agents for which decontamination technology is necessary as well as the name and seller of the decontamination technology furnished to the Government and whether the Secretary has certified such decontamination technology under section 301(b)(4) of the Project BioShield II Act of 2005. The decontamination targets shall include chemical or biological agents or toxins or nuclear or radiological materials.

"(B) AVAILABILITY OF INFORMATION.—The Secretary shall provide such information as the Secretary determines to be necessary to enable the potential manufacturers of terror weapons and infectious disease decontamination technology to structure and focus their research and development programs for the development of such technology.

"(C) REVISIONS.—The Secretary shall revise the list developed under subparagraph (A)

not less often than annually, and make such list available to potential manufacturers of terror weapons and infectious disease decontamination equipment under terms and conditions consistent with the security interests of the United States.

''(D) NO JUDICIAL REVIEW.—Notwithstanding any other provision of law, there shall be no judicial review of the determinations by the Secretary regarding which agents, toxins, or materials are to be included on the list, or revised list, developed under this subsection.

''(E) CONSULTATION.—In developing and revising the list described under subparagraph (A), the Secretary shall consult with the Secretary of Health and Human Services and the Secretary of Defense.

''(F) EXEMPTION.—

''(i) IN GENERAL.—The Secretary may exempt certain information concerning weapons of mass destruction from publication under this subsection if the Secretary determines that such publication would be detrimental to the security of the United States. In providing an exemption under

the preceding sentence, the Secretary shall develop procedures for making such list or information available on a confidential basis to potential manufacturers of countermeasures.

''(ii) SUFFICIENCY OF INFORMATION.—In developing the procedures described in clause (i), the Secretary shall ensure that the information provided to potential manufacturers of countermeasures is sufficient to enable the Federal Government and the manufacturer to determine when such a manufacturer has successfully developed a countermeasure and therefore becomes entitled to the procurement, intellectual property, and liability provisions of title III of the Project BioShield II Act of 2005 (and the amendments made by such title).''.

(d) NEGOTIATIONS WITH FOREIGN GOVERNMENTS.—The Secretary of Homeland Security shall enter into negotiations with foreign governments and organizations to secure coordination and reciprocity among the applicable regulatory agencies responsible for approving and licensing countermeasures, including diagnostics, vaccines,

and drugs to prevent, treat, detect, or identify, an infectious disease.

SEC. 203. ANNUAL REPORT.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) (as amended by sections 202, 1401, 1631, 1901, 2101, and 2102) is amended by inserting after section 319F–8 (as added by section 1631) the following:

"SEC. 319F–9. ANNUAL REPORT.

"(a) IN GENERAL.—

"(1) SUBMISSION OF REPORT.—Not later than January 1, 2006, and each January 1 thereafter, the Secretary shall submit to the appropriate committees of Congress, and make available to the public, a report concerning the implementation of sections 319F–4 through 319F–8 and the amendments made by title III of the Project BioShield II Act of 2005.

"(2) CONTENT OF REPORT.—Reports under paragraph (1) shall include—

"(A) an assessment of whether the incentives provided for under sections 319F–4 through 319F–8 and such amendments are sufficient, as determined by the Secretary, to induce the biotechnology, pharmaceutical, device,

and research tool industries to modify their ongoing research priorities and devote management and scientific talent to researching the development of priority countermeasures, detections equipment, diagnostics, research tools, or drugs intended to directly prevent or treat the pathological and physiological effects of exposures to biological, chemical, nuclear, radiological, and other emerging bioterrorist threats and infectious diseases;

''(B) an assessment of whether such incentives are sufficient, as determined by the Secretary, to address the sensitivity of such industries to the possibility of challenges to their prices and patents and the terms of sales that may arise when the Federal Government is an oligopoly or monopoly purchaser;

''(C) an assessment of whether such incentives are likely to lead to the development of countermeasures and implementation through the qualified clinical countermeasures delivery centers to prepare the United States in the event of the use by terrorists and others of biological, chemical, nuclear, or radiological weapons against military or intelligence, Govern-

ment, and civilian population of the United States;

"(D) an assessment of whether such incentives will lead to the development of research tools;

"(E) an assessment of whether such provisions are achieving the goal of securing the United States from bioterror attacks and infectious disease outbreaks;

"(F) an assessment of whether the incentivies of the Project BioShield II Act of 2005 are being abused by sponsors seeking expanded market protection for non-countermeasure products based on the development of countermeasures that are marginally useful or that require minimal research and development efforts;

"(G) an accounting of the additional healthcare costs to consumers, healthcare providers, and government payors due to the application of the marketing protection incentivies of such Act;

"(H) a description of how such incentives for private sector research relate to the provi-

sion of public funding for the development of countermeasures; and

''(I) recommendations to increase or decrease the effectiveness of such incentives.

''(b) LIMITATION ON PUBLICATION.—The Secretary may exempt information from disclosure to the public under subsection (a) if the Secretary determines that such publication may be detrimental to the security of the United States. Such determinations by the Secretary shall not be subject to judicial review.''.

SEC. 204. USE OF FUNDS; REQUIREMENTS OF MANUFACTURERS.

(a) IN GENERAL.—The Secretary of Health and Human Services may use funds appropriated for the Strategic National Stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) or under any other provision of law for the storage, maintenance, security, rotation, and transport of any material purchased for such stockpile.

(b) REQUIREMENTS OF MANUFACTURERS.—The Secretary of Health and Humans Services shall provide to manufacturers, to the extent practicable, the logistical and operational requirements of countermeasures prior to their development and acquisition. The logistical and operational requirements shall consider public health needs as

well as requirements for storage, maintenance, security, rotation, and transport of any countermeasures purchased under the authority of the Project BioShield Act of 2004.

TITLE III—AMENDMENTS TO THE PROJECT BIOSHIELD ACT OF 2004 REGARDING INCENTIVES TO ESTABLISH BIODEFENSE, INFECTIOUS DISEASE, VACCINE, AND RESEARCH TOOL INDUSTRIES

Subtitle A—Certification of Successful Development

SEC. 301. CERTIFICATION OF SUCCESSFUL DEVELOPMENT.

(a) DEFINITIONS.—For purposes of this title, the term ''countermeasure'' has the meaning given that term in section 319F–3 of the Public Health Service Act (as added by section 101), and the terms ''countermeasure product'', ''eligible patent'' and ''designated product'' have the meanings given such terms in section 156(a) of title 35, United States Code (as added by section 331).

(b) CERTIFICATION REQUIREMENTS.—

(1) IN GENERAL.—An entity described in paragraph (2) may submit to the Secretary of Health and Human Services (referred to in this subtitle as the ''Secretary'') with respect to agreements for pro-

curement entered into under section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a or 247d–6b), or to the Secretary of Homeland Security with respect to agreements for procurement entered into under section 512 of the Homeland Security Act of 2002 (as added by section 202), an application for certification that—

(A) the entity may receive a patent term extension under the provisions of section 158 of title 35, United States Code (as added by section 331), and the duration of any such extension; and

(B) the entity has successfully developed a countermeasure under an agreement described in paragraph (2)(C).

(2) ENTITY DESCRIBED.—An entity described under this paragraph is an entity that—

(A) operates a private sector establishment;

(B) is engaged in the conduct of research to develop a countermeasure; and

(C) enters into an agreement for procurement with the Secretary under the authority provided in section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a

or 247d–6b), or with the Secretary of Homeland Security under section 512 of the Homeland Security Act of 2002 (as added by section 101).

(3) SUCCESSFUL DEVELOPMENT OF A COUNTERMEASURE.—For the purposes of this section, an entity shall be deemed to have successfully developed a countermeasure if, after the date the entity enters into an agreement for procurement with the Secretary under the authority provided in section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a or 247d–6b), or with the Secretary of Homeland Security under section 512 of the Homeland Security Act of 2002 as added by section 101, either—

(A) the entity has met the requirements specified in the contract for procurement under section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a or 247d–6b)) or under section 512 of the Homeland Security Act of 2002; or

(B) the countermeasure has been approved under sections 505 or 513 of the Federal Food Drug and Cosmetic Act (21 U.S.C. 355) or sec-

tion 351 of the Public Health Service Act; (42 U.S.C. 262), as appropriate.

(4) CERTIFICATIONS BY SECRETARY.—

(A) CERTIFICATION AS TO ELIGIBILITY FOR SPECIAL PATENT TERM EXTENSION.—

(i) IN GENERAL.—An entity, prior to the date it has successfully developed a countermeasure product, may request that the Secretary determine if the entity is entitled to receive an extension of the term of an eligible patent under section 158 of title 35, United States Code (as added by section 331), and the duration of any such extension.

(ii) FACTORS CONSIDERED.—The Secretary shall consider the following factors in making the determinations specified in clause (i)—

(I) the nature of the terror threats to be countered and the importance of developing the countermeasures in question to respond to such threat;

(II) the difficulty, risk, and expense likely to be associated with the development of such countermeasure;

(III) the existence or non-existence of practical alternatives to the countermeasure to be developed;

(IV) whether review of the safety and effectiveness of the countermeasure product will require reports from clinical investigations of the countermeasure product; and

(V) the impact of the patent extension on consumers and healthcare providers.

(iii) LIMITATION.—The Secretary may determine that an extension under this section is available only if the countermeasure product involved—

(I) contains an active ingredient (including any ester or salt of the active ingredient) which has not been approved in another application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)); and

(II) is superior to a previously available drug, antibiotic drug, biological product, device, detection technology, or research tool.

(iv) LIMITATION ON EXTENSIONS.—Any extension authorized by the Secretary shall not exceed 2 years, and shall not be less than 6 months, in duration.

(v) WRITTEN DETERMINATION.—The Secretary shall provide an entity that requests a determination under clause (i) with a written determination on the eligibility of that entity for a patent term extension under section 158 of title 35, United States Code (as added by section 331), and the duration of any such extension.

(vi) EFFECT OF SECTION.—The Secretary shall promulgate regulations to give effect to this section.

(B) WRITTEN NOTICE OF ENTITY DEVELOPING COUNTERMEASURE.—

(i) IN GENERAL.—Not later than 180 days after entering a contract with the Secretary of Health and Human Services

under section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a or 247d–6b) or with the Secretary of Homeland Security under section 512 of the Homeland Security Act of 2002 (as added by section 101) for the procurement of a countermeasure for which the Secretary of Health and Human Services or the Secretary of Homeland Security, as appropriate, has determined that a patent extension is available under section 158 of title 35, United States Code (as added by section 331), the entity that enters such contract shall notify such appropriate Secretary of the patent that would be extended if such entity received a certification under section 301(b)(4)(A).

(ii) PUBLICATION OF INFORMATION.—The Secretary of Health and Human Services, with respect to a contract under such section 319F–1 or 319F–2 of the Public Health Service Act, or the Secretary of Homeland Security, with respect to a contract under such section 512 of the Homeland Security Act of 2002, shall publish in

the Federal Register the information provided in a notification received under clause (i).

(iii) IRREVOCABLE ELECTION.—An submission of a notification by an entity under clause (i) shall constitute an irrevocable election of the patent extended under section 158 of title 35, United States Code, except that such entity may elect to restore the term of the eligible patent under section 156a of title 35, United States Code, instead of extending the term of the patent under such section 158 on the basis of the successful development of the countermeasure.

(C) CERTIFICATION AS TO SUCCESSFUL DEVELOPMENT.—With respect to an application for certification submitted by an entity in accordance with the terms of the agreement for procurement described under paragraph (2)(C), the Secretary or the Secretary of Homeland Security, as appropriate, shall—

(i) determine if the entity has successfully developed the countermeasure involved;

(ii) provide the notice required under subparagraph (B);

(iii) approve or deny the application for certification; and

(iv) notify such entity of and publish such approval or denial, and the reasons therefore.

(D) EFFECTS OF CERTIFICATION.—If the Secretary or Secretary of Homeland Security certifies the application of an entity under paragraph (3)(A), such entity—

(i) shall receive payment under the contract described in paragraph (2)(C);

(ii) may utilize the patent restoration and extension protection under section 156a and 158 of title 35, United States Code (as added by section 331);

(iii) may utilize the marketing exclusivity provisions of section 505(c)(3)(E) and 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E) and 21 U.S.C. 355(j)(5)(E)); and

(iv) may utilize the liability protections described under this title (and the amendments made by this title).

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to restrict the authority of the Secretary (with respect to procurement agreements under section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a or 247d–6b)) or the Secretary of Homeland Security (with respect to procurement agreements under section 512 of the Homeland Security Act of 2002 (as added by section 101) to permit an entity to utilize the liability protections described under this title (and the amendments made by this title) or to receive payment under the agreement described in subsection (b)(2)(C) prior to the approval of the application for certification submitted by the entity pursuant to the terms of such agreement.

(d) JUDICIAL REVIEW.—A determination by the Secretary or the Secretary of Homeland Security, as appropriate, under subsection (b) shall constitute final agency action subject to judicial review. A prevailing plaintiff in an action challenging an adverse determination by the Secretary or Secretary of Homeland Security under such subsection may be awarded reasonable attorneys fees under section 2412 of title 28, United States Code.

Subtitle B—Federal Tax Incentives

SEC. 311. GENERAL PROVISIONS.

(a) IN GENERAL.—Any entity which enters into a contract for procurement with the Secretary under the authority provided in section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a or 247d–6b) or under section 512 of the Homeland Security Act of 2002 (as added by section 101) may irrevocably elect 1 of the following Federal tax incentives to fund research with respect to each contract to develop countermeasures (as that term is defined in section 319F–3 of the Public Health Service Act (as added by section 202)):

(1) RESEARCH AND DEVELOPMENT LIMITED PARTNERSHIPS TO FUND COUNTERMEASURE RESEARCH.—The entity may establish a limited partnership for the countermeasures, but only if such entity is a qualified small business as determined under section 1202(d) of the Internal Revenue Code of 1986, by substituting ''$750,000,000'' for ''$50,000,000'' each place it appears. For purposes of the Internal Revenue Code of 1986, section 469 of such Code shall not apply with respect to a limited partnership established under this paragraph.

(2) CAPITAL GAINS EXCLUSION FOR INVESTORS TO FUND COUNTERMEASURE RESEARCH.—The enti-

ty may issue a class of stock for the countermeasures under section 1202 of the Internal Revenue Code of 1986 with the following modifications:

(A) INCREASED EXCLUSION FOR NONCORPORATE TAXPAYERS.—Subsection (a) of section 1202 of such Code shall be applied by substituting ''100 percent'' for ''50 percent''.

(B) APPLICATION TO CORPORATE TAXPAYERS.—Subsection (a) of section 1202 of such Code shall be applied without regard to the phrase ''other than a corporation''.

(C) STOCK OF LARGER BUSINESSES ELIGIBLE FOR EXCLUSION.—Paragraph (1) of section 1202(d) of such Code (defining qualified small business) shall be applied by substituting ''$750,000,000'' for ''$50,000,000'' each place it appears.

(D) REDUCTION IN HOLDING PERIOD.—Subsection (a) of section 1202 of such Code shall be applied by substituting ''3 years'' for ''5 years''.

(E) NONAPPLICATION OF PER-ISSUER LIMITATION.—Section 1202 of such Code shall be applied without regard to subsection (b) (relat-

ing to per-issuer limitations on taxpayer's eligible gain).

(F) MODIFICATION OF WORKING CAPITAL LIMITATION.—Section 1202(e)(6) of such Code shall be applied—

(i) in subparagraph (B), by substituting ''5 years'' for ''2 years'', and

(ii) without regard to the last sentence.

(G) NONAPPLICATION OF MINIMUM TAX PREFERENCE.—Section 57(a) of such Code shall be applied without regard to paragraph (7).

(3) TAX CREDITS TO FUND COUNTERMEASURE RESEARCH.—The entity may be eligible for the tax credits provided for in section 312.

(b) REPORTING; RECAPTURE.—

(1) REPORTING.—Each entity described in subsection (a) shall submit to the Secretary and the Secretary of the Treasury such information regarding its election of any tax incentive under this section with respect to any contract described in subsection (a) as the Director of the National Institutes of Health and the Secretary of Health and Human Services determine necessary to carry out the en-

forcement provisions prescribed under paragraph (2).

(2) RECAPTURE.—The Secretary of the Treasury, in consultation with the Director of the National Institutes of Health and the Secretary of Health and Human Services, shall provide for the recapture of any tax benefits resulting from any elected tax incentive under this section if the resulting research is for a purpose other than that specified in such contract.

(c) EFFECTIVE DATE.—The provisions of this section shall apply to taxable years beginning after December 31, 2004.

SEC. 312. TAX CREDITS.

(a) AMENDMENTS TO THE INTERNAL REVENUE CODE.—

(1) TAX CREDIT TO FUND COUNTERMEASURE RESEARCH.—

(A) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business-related credits) is amended by adding at the end the following new section:

"SEC. 45J. CREDIT FOR MEDICAL RESEARCH RELATED TO DEVELOPING COUNTERMEASURES.

''(a) GENERAL RULE.—For purposes of section 38, in the case of any entity described in section 311(a) of the Project BioShield II Act of 2005 which makes an election under such section to apply this section, the countermeasures research credit determined under this section for the taxable year is an amount equal to 35 percent of the eligible countermeasures research expenses for the taxable year.

''(b) ELIGIBLE COUNTERMEASURES RESEARCH EXPENSES.—For purposes of this section—

''(1) ELIGIBLE COUNTERMEASURES RESEARCH EXPENSES.—

''(A) IN GENERAL.—Except as otherwise provided in this paragraph, the term 'eligible countermeasures research expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year with respect to any contract described in section 311(a) of the Project BioShield II Act of 2005 which would be described in subsection (b) of section 41 if such subsection were applied with the modifications set forth in subparagraph (B).

''(B) MODIFICATIONS; INCREASED INCENTIVE FOR CONTRACT RESEARCH PAYMENTS.—

For purposes of subparagraph (A), subsection (b) of section 41 shall be applied—

"(i) by substituting 'eligible countermeasures research' for 'qualified research' each place it appears in paragraphs (2) and (3) of such subsection, and

"(ii) by substituting '100 percent' for '65 percent' in paragraph (3)(A) of such subsection.

"(C) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term 'eligible countermeasures research expenses' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

"(2) COUNTERMEASURES RESEARCH.—The term 'countermeasures research' means research conducted by an entity with respect to the development of countermeasures (as defined in section 319F–3 of the Public Health Service Act).

"(c) COORDINATION WITH CREDIT FOR INCREASING RESEARCH EXPENDITURES.—

"(1) IN GENERAL.—Except as provided in paragraph (2), any eligible countermeasures research expenses for a taxable year to which an election under

this section applies shall not be taken into account for purposes of determining the credit allowable under section 41 for such taxable year.

''(2) EXPENSES INCLUDED IN DETERMINING BASE PERIOD RESEARCH EXPENSES.—Any eligible countermeasures research expenses for any taxable year which are qualified research expenses (within the meaning of section 41(b)) shall be taken into account in determining base period research expenses for purposes of applying section 41 to subsequent taxable years.

''(d) COORDINATION WITH CREDIT FOR CLINICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR RARE DISEASES.—Any eligible countermeasures research expense for a taxable year shall not be taken into account for purposes of determining the credit allowable under section 45C for such taxable year.

''(e) SPECIAL RULES.—

''(1) PRE-CLINICAL RESEARCH.—No credit shall be allowed under this section for pre-clinical research unless such research is pursuant to a research plan an abstract of which has been filed with the Food and Drug Administration before the beginning of such year. This paragraph shall be waived for any research that is pursuant to a research plan

or abstract that has been filed with the Food and Drug Administration not later than 270 days after the date of enactment of this section. The Secretary of Health and Human Services shall prescribe regulations specifying the requirements for such plans and procedures for filing under this paragraph.

''(2) CERTAIN RULES MADE APPLICABLE.—Rules similar to the rules of paragraphs (1) and (2) of section 41(f) shall apply for purposes of this section.''.

(B) INCLUSION IN GENERAL BUSINESS CREDIT.—Section 38(b) of such Code is amended by striking ''plus'' at the end of paragraph (18), by striking the period at the end of paragraph (19) and inserting '', plus'', and by adding at the end the following new paragraph:

''(20) the countermeasures research credit determined under section 45J.''.

(C) DENIAL OF DOUBLE BENEFIT.—Section 280C of such Code is amended by adding at the end the following new subsection:

''(e) CREDIT FOR ELIGIBLE COUNTERMEASURES RESEARCH EXPENSES.—

''(1) IN GENERAL.—No deduction shall be allowed for that portion of the eligible counter-

measures research expenses (as defined in section 45J(b)) otherwise allowable as a deduction for the taxable year which is equal to the amount of the credit determined for such taxable year under section 45J(a).

''(2) CERTAIN RULES TO APPLY.—Rules similar to the rules of paragraphs (2), (3), and (4) of subsection (c) shall apply for purposes of this subsection.''.

(D) DEDUCTION FOR UNUSED PORTION OF CREDIT.—Section 196(c) of such Code (defining qualified business credits) is amended by striking ''and'' at the end of paragraph (11), by striking the period at the end of paragraph (12) and inserting '', and'', and by adding at the end the following new paragraph:

''(13) the countermeasures research credit determined under section 45J(a) (other than such credit determined under the rules of section 280C(e)(2)).''.

(E) TECHNICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of such Code is amended by adding at the end the following new item:

''Sec. 45J. Credit for medical research related to developing countermeasures.''.

(2) TAX CREDIT TO FUND COUNTERMEASURE RESEARCH AT CERTAIN QUALIFIED NON-PROFIT AND ACADEMIC INSTITUTIONS INCLUDING TEACHING HOSPITALS.—

(A) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business related credits) is amended by inserting after section 41 the following:

"SEC. 41A. CREDIT FOR COUNTERMEASURES RESEARCH EXPENSES.

''(a) GENERAL RULE.—For purposes of section 38, in the case of any entity described in section 311(a) of the Project BioShield II Act of 2005 which makes an election under such section to apply this section, the countermeasures research credit determined under this section for the taxable year shall be an amount equal to 35 percent of the excess (if any) of—

''(1) the eligible countermeasures research expenses for the taxable year, over

''(2) the countermeasures base period amount.

''(b) ELIGIBLE COUNTERMEASURES RESEARCH EXPENSES.—For purposes of this section—

''(1) IN GENERAL.—The term 'eligible countermeasures research expenses' means the amounts

which are paid or incurred by the taxpayer during the taxable year directly or indirectly to any qualified nonprofit or academic institution for countermeasures research activities with respect to any contract described in section 311(a) of the Project BioShield II Act of 2005.

''(2) COUNTERMEASURES RESEARCH ACTIVITIES.—

''(A) IN GENERAL.—The term 'countermeasures research activities' means research conducted by an entity with respect to the development of countermeasures (as defined in section 319F–3 of the Public Health Service Act), conducted at any qualified nonprofit or academic institution in the development of any product, which occurs before—

''(i) the date on which an application with respect to such product is approved under section 505(b), 506, or 507 of the Federal Food, Drug, and Cosmetic Act,

''(ii) the date on which a license for such product is issued under section 351 of the Public Health Service Act, or

''(iii) the date classification or approval of such product which is a device in-

tended for human use is given under section 513, 514, or 515 of the Federal Food, Drug, and Cosmetic Act.

"(B) PRODUCT.—The term 'product' means any drug, biologic, medical device, or research tool.

"(3) QUALIFIED NONPROFIT OR ACADEMIC INSTITUTION.—The term 'qualified nonprofit or academic institution' means any of the following institutions:

"(A) EDUCATIONAL INSTITUTION.—A qualified organization described in section 170(b)(1)(A)(iii) which is owned or affiliated with an institution of higher education as described in section 3304(f).

"(B) TEACHING HOSPITAL.—A teaching hospital which—

"(i) is publicly supported or owned by an organization described in section 501(c)(3), and

"(ii) is affiliated with an organization meeting the requirements of subparagraph (A).

"(C) FOUNDATION.—A medical research organization described in section 501(c)(3)

(other than a private foundation) which is affiliated with, or owned by—

"(i) an organization meeting the requirements of subparagraph (A), or

"(ii) a teaching hospital meeting the requirements of subparagraph (B).

"(D) CHARITABLE RESEARCH HOSPITAL.—A hospital that is designated as a cancer center by the National Cancer Institute.

"(E) OTHER INSTITUTIONS.—A qualified organization (as defined in section 41(e)(6)).

"(4) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term 'eligible countermeasures research expenses' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

"(c) COUNTERMEASURES RESEARCH BASE PERIOD AMOUNT.—For purposes of this section, the term 'countermeasures research base period amount' means the average annual eligible countermeasures research expenses paid by the taxpayer during the 3-taxable year period ending with the taxable year immediately preceding the first taxable year of the taxpayer beginning after December 31, 2004.

''(d) SPECIAL RULES.—

''(1) CERTAIN RULES MADE APPLICABLE.—Rules similar to the rules of subsections (f) and (g) of section 41 shall apply for purposes of this section.

''(2) COORDINATION WITH CREDIT FOR INCREASING RESEARCH EXPENDITURES AND WITH CREDIT FOR CLINICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR RARE DISEASES.—Any eligible countermeasures research expense for a taxable year shall not be taken into account for purposes of determining the credit allowable under section 41 or 45C for such taxable year.

''(3) ELIGIBLE COUNTERMEASURES RESEARCH EXPENSES NOT TREATED AS UNRELATED BUSINESS TAXABLE INCOME.—For purposes of section 511, eligible countermeasures research expenses paid or incurred by the taxpayer directly or indirectly to any qualified non-profit or academic institution shall not be considered unrelated business taxable income of such institution.''.

(B) CREDIT TO BE PART OF GENERAL BUSINESS CREDIT.—Section 38(b) of such Code (relating to current year business credits), as amended by this section, is amended by striking ''plus'' at the end of paragraph (19), by strik-

ing the period at the end of paragraph (20) and inserting ", plus", and by adding at the end the following:

"(21) the countermeasures research credit determined under section 41A(a).".

(C) DENIAL OF DOUBLE BENEFIT.—Section 280C of such Code, as amended by this section, is amended by adding at the end the following new subsection:

"(f) CREDIT FOR COUNTERMEASURES RESEARCH EXPENSES.—

"(1) IN GENERAL.—No deduction shall be allowed for that portion of the eligible countermeasures research expenses (as defined in section 41A(b)) otherwise allowable as a deduction for the taxable year which is equal to the amount of the credit determined for such taxable year under section 41A(a).

"(2) CERTAIN RULES TO APPLY.—Rules similar to the rules of paragraphs (2), (3), and (4) of subsection (c) shall apply for purposes of this subsection.".

(D) DEDUCTION FOR UNUSED PORTION OF CREDIT.—Section 196(c) of such Code (defining qualified business credits), as amended by this

section, is amended by striking ''and'' at the end of paragraph (12), by striking the period at the end of paragraph (13) and inserting '', and'', and by adding at the end the following new paragraph:

''(14) the countermeasures research expenses credit determined under section 41A(a) (other than such credit determined under the rules of section 280C(f)(2)),''.

(E) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of such Code is amended by adding after the item relating to section 41 the following:

''Sec. 41A. Credit for countermeasures research expenses.''.

(3) COUNTERMEASURES EQUITY TAX CREDIT.—

(A) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business-related credits), as amended by this section, is amended by adding at the end the following new section:

''SEC. 45K. COUNTERMEASURES EQUITY TAX CREDIT.

''(a) ALLOWANCE OF CREDIT.—

''(1) GENERAL RULE.—For purposes of section 38, in the case of a taxpayer who holds a qualified

countermeasures equity investment on a credit allowance date of such investment which occurs during the taxable year, the countermeasures equity tax credit determined under this section for such taxable year is an amount equal to the applicable percentage of the amount paid to the qualified countermeasures company solely in exchange for its stock at original issue.

''(2) APPLICABLE PERCENTAGE.—For purposes of paragraph (1), the applicable percentage is 40 percent.

''(3) CREDIT ALLOWANCE DATE.—For purposes of paragraph (1), the term 'credit allowance date' means, with respect to any qualified countermeasures equity investment—

''(A) the date on which such investment is initially made, and

''(B) each of the 3 anniversary dates of such date thereafter.

''(b) QUALIFIED COUNTERMEASURES EQUITY INVESTMENT.—For purposes of this section—

''(1) IN GENERAL.—The term 'qualified countermeasures equity investment' means any equity investment in a qualified countermeasures company if—

''(A) such investment is acquired by the taxpayer at its original issue (directly or through an underwriter) solely in exchange for cash,

''(B) not less than ½ of such cash is used by the qualified countermeasures company with respect to any contract described in section 311(a) of the Project BioShield II Act of 2005 or efforts reasonably leading to such contract (such as generation of preliminary data or prototype development), and

''(C) such investment is designated for purposes of this section by the qualified countermeasures company.

Such term shall not include any equity investment issued by a qualified countermeasures company more than 5 years after the date that such company receives an allocation under subsection (d). Any allocation not used within such 5-year period may be reallocated by the Secretary under subsection (d).

''(2) LIMITATION.—The maximum amount of equity investments issued by a qualified countermeasures company which may be designated under paragraph (1)(C) by such company shall not exceed

the portion of the limitation amount allocated under subsection (f) to such company.

''(3) TREATMENT OF SUBSEQUENT PURCHASERS.—The term 'qualified equity investment' includes any equity investment which would (but for paragraph (1)(A)) be a qualified equity investment in the hands of the taxpayer if such investment was a qualified equity investment in the hands of a prior holder.

''(4) REDEMPTIONS.—A rule similar to the rule of section 1202(c)(3) shall apply for purposes of this subsection.

''(5) EQUITY INVESTMENT.—The term 'equity investment' means any stock (other than nonqualified preferred stock as defined in section 351(g)(2)) in an entity which is a corporation.

''(c) QUALIFIED COUNTERMEASURES COMPANY.—For purposes of this section the term 'qualified countermeasures company' means any domestic corporation subject to tax under subchapter C of this chapter if such company has entered into a procurement contract with the Secretary of Health and Human Services under section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a or 247d–6b) or with the Secretary of

Homeland Security under section 512 of the Homeland Security Act of 2002.

''(d) NATIONAL LIMITATION ON AMOUNT OF INVESTMENTS DESIGNATED.—

''(1) IN GENERAL.—There is a qualified countermeasures equity tax credit limitation for each calendar year. Such limitation is $100,000,000 for each calendar year 2005 through 2009.

''(2) ALLOCATION OF LIMITATION.—The limitation under paragraph (1) shall be allocated by the Secretary among qualified countermeasures companies selected by the Secretary. In making allocations under the preceding sentence, the Secretary shall give priority to the extent to which it is reasonably anticipated that a qualified countermeasures company would have insufficient taxable income and tax liability to utilize research tax credits and other tax incentives provided by sections 311 and 312 of the Project BioShield II Act of 2005.

''(3) CARRYOVER OF UNUSED LIMITATION.—If the qualified countermeasures equity tax credit limitation for any calendar year exceeds the aggregate amount allocated under paragraph (2) for such year, such limitation for the succeeding calendar year shall be increased by the amount of such excess. No

amount may be carried under the preceding sentence to any calendar year after 2014.

''(e) RECAPTURE OF CREDIT IN CERTAIN CASES.—

''(1) IN GENERAL.—If, at any time during the 4-year period beginning on the date of the original issue of a qualified countermeasures equity investment in a qualified countermeasures company, there is a recapture event with respect to such investment, then the tax imposed by this chapter for the taxable year in which such event occurs shall be increased by the credit recapture amount.

''(2) CREDIT RECAPTURE AMOUNT.—For purposes of paragraph (1), the credit recapture amount is an amount equal to the sum of—

''(A) the aggregate decrease in the credits allowed to the taxpayer under section 38 for all prior taxable years which would have resulted if no credit had been determined under this section with respect to such investment, plus

''(B) interest at the underpayment rate established under section 6621 on the amount determined under subparagraph (A) for each prior taxable year for the period beginning on the due date for filing the return for the prior taxable year involved.

No deduction shall be allowed under this chapter for interest described in subparagraph (B).

''(3) RECAPTURE EVENT.—For purposes of paragraph (1), there is a recapture event with respect to a qualified countermeasures equity investment in a qualified countermeasures company if—

''(A) such company ceases to be a qualified countermeasures company, or

''(B) such investment is redeemed by such company.

''(4) SPECIAL RULES.—

''(A) TAX BENEFIT RULE.—The tax for the taxable year shall be increased under paragraph (1) only with respect to credits allowed by reason of this section which were used to reduce tax liability. In the case of credits not so used to reduce tax liability, the carryforwards and carrybacks under section 39 shall be appropriately adjusted.

''(B) NO CREDITS AGAINST TAX.—Any increase in tax under this subsection shall not be treated as a tax imposed by this chapter for purposes of determining the amount of any credit under this chapter or for purposes of section 55.

''(f) BASIS REDUCTION.—The basis of any qualified countermeasures equity investment shall be reduced by the amount of any credit determined under this section with respect to such investment. This subsection shall not apply for purposes of sections 1202, 1400B, and 1400F.

''(g) REGULATIONS.—The Secretary shall prescribe such regulations as may be appropriate to carry out this section, including regulations which—

''(1) prevent the abuse of the purposes of this section,

''(2) impose appropriate reporting requirements, and

''(3) apply the provisions of this section to newly formed entities.''.

(B) CREDIT TO BE PART OF GENERAL BUSINESS CREDIT.—Section 38(b) of such Code (relating to current year business credits), as amended by this section, is amended by striking ''plus'' at the end of paragraph (20), by striking the period at the end of paragraph (21) and inserting '', plus'', and by adding at the end the following:

''(22) the countermeasures equity investment credit determined under section 45K(a).''.

(C) DEDUCTION FOR UNUSED PORTION OF CREDIT.—Section 196(c) of such Code (defining qualified business credits), as amended by this section, is amended by striking ''and'' at the end of paragraph (13), by striking the period at the end of paragraph (14) and inserting '', and'', and by adding at the end the following new paragraph:

''(15) the countermeasures equity investment credit determined under section 45K(a),''.

(D) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of such Code is amended by adding after the item relating to section 41 the following:

''Sec. 45K. Countermeasures equity tax credit.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2004.

Subtitle C—Patent Protections

SEC. 331. PATENT TERM RESTORATION AND EXTENSION AND EXCLUSIVE MARKETING.

(a) LIMITATION.—A private entity may utilize the patent term restoration and extension and exclusive marketing provisions described in this subtitle if such private entity—

(1) is an entity described under section 301(b)(2);

(2) has had an application for certification approved by the Secretary of Health and Human Services or the Secretary of Homeland Security, as appropriate, under section 301(b)(4)(C); and

(3)(A) has received approval of the countermeasure by the Food and Drug Administration; or

(B) section 319F–2(e) applies.

(b) RESTORATION OF PATENT TERMS RELATING TO COUNTERMEASURES.—

(1) IN GENERAL.—Chapter 14 of title 35, United States Code, is amended by inserting after section 156 the following:

"§ 156a. Restoration of patent terms relating to countermeasure products

''(a) DEFINITIONS.—In this section, the term—

''(1) 'countermeasure product' means a countermeasure, as that term is defined in section 319F–3(a)(2) of the Public Health Service Act, that is a—

''(A) new drug, antibiotic drug, or device, as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

''(B) biological product, as such term is defined in section 351 of the Public Health Service Act (42 U.S.C. 262);

''(2) 'regulatory review period' means the period of time that—

''(A) starts on the date that is the later of—

''(i) the date that an eligible patent sought to be extended under this section is filed;

''(ii) if the countermeasure product is a drug, antibiotic drug, or biological product, the date that an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective for the product; or

''(iii) if the countermeasure product is a device, the date that an investigational device exception is approved under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) became effective for the product; and

''(B) ends on the date that is—

''(i) in the case of a drug or antibiotic drug, the date on which an application

submitted for the drug or antibiotic drug under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) is approved;

''(ii) in the case of a biological product, the date on which an application submitted for the biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) is approved;

''(iii) in the case of a device, the date on which an application submitted for the device under section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is approved; or

''(iv) if an application is submitted under subsection (c)(3) prior to any of the dates specified in clauses (i) through (iii), the date that the countermeasure product became eligible for purchase under a contract for procurement under section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a or 247d–6b)) or under section 512 of the Homeland Security Act of 2002;

''(3) 'eligible patent' means a patent that—

''(A) claims a countermeasure product that has been successfully developed as specified in section 301(b)(3) of the Research Act, or an active ingredient of such product, or a process of making or method of using such product or the active ingredient of such product for the countermeasure use that has been approved by the Food and Drug Administration; and

''(B) is owned by, or licensed to, an entity that has been certified as having successfully developed the countermeasure section 301(b)(4)(C) of the Research Act; and

''(4) 'Research Act' means the Project BioShield II Act of 2005.

''(b) PATENT TERM RESTORATION.—The term of an eligible patent shall be restored by a period equal to the number of days in the regulatory review period if, with respect to the patent that is the basis of the application—

''(1) an application under subsection (c) is submitted to the Director by either the owner of record of the patent, or its agent, on or before the later of—

''(A) the date specified in subsection (c)(3); or

"(B) 45 days after the date of issuance of the patent;

"(2) the patent has not been previously restored under this section, or extended under section 156 or 158;

"(3) the term of the patent has not expired before the date that the application is submitted to the Director; and

"(4) the regulatory review period for the countermeasure product—

"(A) has not been relied upon to support an application to extend the term of another patent under this section or under section 156; and

"(B) did not commence before the date of enactment of the Research Act.

"(c) ADMINISTRATIVE PROVISIONS.—

"(1) IN GENERAL.—To obtain a restoration of the term of a patent under this section, the owner of record of the patent or the agent of the owner shall submit an application to the Director.

"(2) CONTENT.—The application shall contain—

"(A) a description of the approved countermeasure product and the Federal statute under which regulatory review occurred;

"(B) the identity of the patent for which a restoration is sought; and

"(C) such other information as the Director may require.

"(3) SUBMISSION OF APPLICATION.—An application under this section shall be submitted to the Director not later than 60 days after the last of the following dates:

"(A) The date that the product became eligible for purchase under a contract for procurement under section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a or 247d–6b)) or under section 512 of the Homeland Security Act of 2002.

"(B) The date that an application under section 505 of the Federal Food Drug and Cosmetic Act was approved for the drug or antibiotic drug.

"(C) The date that an application under section 351 of the Public Health Service Act was approved for the biological product.

"(D) The date that an application under section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) was approved for the device.

"(4) PUBLICATION OF APPLICATIONS BY THE SECRETARY.—Immediately under receipt of an application for patent restoration under this subsection, the Director shall publish the application and provide a reasonable period of time for interested parties to submit comments with respect to the application.

"(5) IRREVOCABLE ELECTION.—The submission of an application under this section is an irrevocable election of the application of this section to the patent that is the basis of the application. A patent that has been the basis of an application made under this section may not be the subject of an application made under section 156 or 158.

"(d) LIMITATIONS.—A patent that is the subject of an application filed under subsection (c) may not be restored under this section if—

"(1) the regulatory review period for the countermeasure product was commenced before the date of enactment of the Research Act;

''(2) the patent that is the basis of the application under this section expired before the date of enactment of the Research Act; or

''(3) a patent which has been extended under section 156 of this title prior to the date of enactment of the Research Act claims the countermeasure product, an active ingredient of the countermeasure product, a method of using the countermeasure product, a method of using an active ingredient of the countermeasure product, or making the countermeasure.''.

(2) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 14 of title 35, United States Code, is amended by inserting after the item relating to section 156 the following:

''156a. Restoration of patent terms relating to countermeasure products.''.

(c) EXTENSION OF PATENT TERMS RELATING TO COUNTERMEASURE PRODUCTS.—

(1) IN GENERAL.—Chapter 14 of title 35, United States Code, is amended by adding at the end the following:

''§ 158. Extension of patent terms relating to countermeasure products

''(a) DEFINITIONS.—In this section, the term—

"(1) 'countermeasure product' means a countermeasure, as that term is defined in 319F–3(a)(2) of the Public Health Service Act, that is a—

"(A) new drug or antibiotic drug, as those terms are defined in section 201 in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), containing an active ingredient (including any ester or salt of the active ingredient) which has not been approved in another application under section 505(b) of that Act (21 U.S.C. 355(b));

"(B) device, as that term is defined in section 201 in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

"(C) biological product, as that term is defined in section 351 of the Public Health Service Act (42 U.S.C. 262);

"(2) 'designated product' means a drug, antibiotic drug, or device, as those terms are defined in section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321), or a biological product, as that term is defined in section 351 of the Public Health Service Act;

"(3) 'eligible patent' means a patent that at the time the eligible entity entered into the contract to

develop such countermeasure product, was owned by or licensed to that eligible entity, and claims a designated product, an active ingredient of a designated product, a method of making or using a designated product or a method of making or using an active ingredient of a designated product;

''(4) 'eligible entity' means a natural or legal person that has—

''(A) successfully developed a countermeasure product;

''(B) been certified as being eligible to receive a patent term extension under this section by section 301(b)(4)(A)(i) of the Research Act;

''(C) been certified as having successfully developed a countermeasure under section 301(b)(4)(C) of the Research Act; and

''(D) entered into a contract for the sale of the countermeasure product under section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a or 247d–6b) or section 512 of the Homeland Security Act of 2002; and

''(5) 'Research Act' means the Project BioShield II Act of 2005.

''(b) PATENT TERM EXTENSION.—The term of an eligible patent shall be extended for the period determined by the Secretary of Health and Human Services in a certification under section 301(b)(4)(A)(i) of the Research Act, in addition to the term which would otherwise apply except for this section, if—

''(1) an application under subsection (c) is submitted to the Director by either the owner of record of the patent or its agent on or before the date specified in subsection (c)(3);

''(2) the patent has not been previously extended under this section, or under section 156 or 156a;

''(3) the applicant has provided written notice and the Secretary has published such information as required under section 301(b)(4)(B) of the Project BioShield II Act of 2005;

''(4) the patent has not expired before the date that the application is submitted;

''(5) the term of no other patent has been extended based on the certification being relied upon by the eligible entity to request extension of the patent; and

''(6) no other patent that claims the designated product, an active ingredient of the designated prod-

uct, a method of making or using a designated product or a method of making or using an active ingredient of a designated product has been extended under this section or under section 156a.

''(c) ADMINISTRATIVE PROVISIONS.—

''(1) IN GENERAL.—To obtain an extension of the term of a patent under this section, the owner of record of the patent or the agent of the owner shall submit an application to the Director.

''(2) CONTENT.—An application filed under this section shall contain—

''(A) a description of the approved countermeasure product and the Federal statute under which regulatory review occurred;

''(B) the identity of the eligible patent for which an extension is sought under this section;

''(C) the identity of the eligible entity and the applicant (if different from the eligible entity);

''(D) the identity of the designated product to which the eligible patent relates;

''(E) information concerning the certification specified in section 301(b)(4)(A)(i) of the Research Act being relied upon as the basis of the extension being requested;

"(F) information indicating that the entity owned or licensed the eligible patent at the time it entered into the contract to develop the countermeaure product; and

"(G) such other information as the Director may require including to establish that the applicant meets the requirements of this section.

"(3) SUBMISSION OF APPLICATION.—An application under this section shall be submitted to the Director within 60 days after the date of the certification specified in section 301(b)(4)(C) of the Research Act that is being relied upon to request extension of the patent that is the subject of the application.

"(d) IRREVOCABLE ELECTION.—The submission of an application under this section is an irrevocable election of the application of this section to the patent that is the basis of the application. A patent that has been the basis of an application made under this section may not be the subject of an application made under sections 156 or 156a.".

(2) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 14 of title

35, United States Code, is amended by adding at the end the following:

"158. Extension of patent terms relating to countermeasure products.".

(d) DISCRETIONARY WAIVER OF MARCH-IN RIGHTS AND EXCLUSIVE LICENSING.—

(1) DISCRETION TO WAIVE MARCH-IN RIGHTS.—

(A) IN GENERAL.—The owner of a patent over which the Government has rights under chapter 18 of title 35, United States Code, may request that a Federal agency under whose funding a subject invention was made may waive rights the Government has under sections 200, 203, and 209 of title 35, United States Code, if—

(i) such entity holds a certification under section 301(b)(4)(C) of the Research Act; and

(ii) the subject invention is related to or will be used to discover, evaluate, produce, manufacture or use the countermeasure, detection equipment, diagnostic, research tool, drug, antibiotic drug, biological product or a device that is the subject of the certification.

(B) REQUESTS.—If a request under subparagraph (A) is made within 90 days after the date of the certification under section 301(b)(4)(C) of the Research Act or the date that the entity obtained title to the patent, the Federal agency shall grant the request.

(2) FEDERALLY OWNED INVENTIONS.—Section 209 of title 35, United States Code, is amended—

(A) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively; and

(B) by inserting after subsection (d) the following:

''(e) TERMS AND CONDITIONS OF EXCLUSIVE LICENSE.—Each exclusive license granted under section 207(a)(2) shall include a provision that, at the discretion of the licensee, the licensee may act as the agent for the licensor with respect to any patent for the licensed invention for purposes of extending a patent under section 156a or 158.''.

(3) COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.—Section 12(b) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(b)) is amended by adding at the end the following:

''(7) Each exclusive license for a patent granted under an agreement entered into under subsection (a)(1) shall include a provision that, at the discretion of the licensee, the licensee may act as the agent for the licensor with respect to that patent for purposes of extending a patent under section 156a or 158 of title 35, United States Code.''.

(4) APPLICABLE LICENSES.—The amendments made by paragraphs (2) and (3) shall apply only to exclusive licenses granted after 60 days after the date of enactment of this Act.

(e) EXCLUSIVE MARKETING.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B, the following:

''SEC. 505C. MARKET EXCLUSIVITY FOR COUNTERMEASURE PRODUCTS.

''(a) IN GENERAL.—Subsection (b) shall apply if the Secretary determines that a new drug is a countermeasure product, as that term is defined in section 156a(a)(1) of title 35, United States Code, that has been successfully developed by an entity that has been certified under section 301(b)(4)(A) of the Project BioShield II Act of 2005.

''(b) EXCLUSIVITY.—With respect to a new drug described in subsection (a)—

''(1)(A)(i) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, shall be 10 years instead of 5 years, and the periods of 4 years, to 48 months, and to 7 and one-half years referred to in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section shall be 9 years, 108 months, and 9 years, respectively; or

''(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, shall be 6 years instead of 3 years; and

''(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) shall be 10 years instead of 7 years.

''(c) SPECIAL RULE FOR UNEXPLOITED COUNTERMEASURES.—If, as of the date that is 45 days before the date on which the periods specified in paragraph (1) or (2) of section 505B expire, there has been no substantial commercial exploitation of the drug, including insubstantial sales of the drug following its approval for marketing, the periods specified in such sections shall be extended by a period of 3 years.''.

SEC. 332. INTERNATIONAL PROTECTION FOR BIOSHIELD INTELLECTUAL PROPERTY.

The Secretary of Commerce, the United States Trade Representative, and the Commissioner of Patents shall ensure in international, bilateral, and multilateral negotiations and agreements, and proceedings before agencies of the World Trade Organization, that—

(1) intellectual property for which restoration of a patent term is granted under section 156a of title 35, United States Code (as added by section 331), or for which an extension of a patent term is granted under section 158 of title 35, United States Code, (as added by section 331) under this Act is not impaired;

(2) substantially similar intellectual property rights granted to the same or related entities as those that qualify for restoration or an extension under such sections are not impaired; and

(3) vigorous enforcement actions and sanctions are taken and imposed with respect to infringement of such intellectual property.

Subtitle D—Liability Protections

SEC. 341. LIABILITY AND COMPENSATION FOR INJURED PARTIES.

(a) THE PUBLIC HEALTH SERVICE ACT AMENDMENTS.—Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended—

(1) in subsection (a), by inserting ''or the manufacture or distribution of a covered countermeasure as defined in subsection (p)'' after ''including the conduct of clinical studies or investigation'';

(2) in the heading of subsection (p), by striking ''ADMINISTRATION OF SMALLPOX COUNTERMEASURES BY HEALTH PROFESSIONALS'' and inserting ''MANUFACTURE, DISTRIBUTION, AND ADMINISTRATION OF COVERED COUNTERMEASURES'';

(3) in subsection (p)(1)—

(A) by inserting ''manufacture, distribution, or'' after ''liability arising out of'';

(B) by striking ''against smallpox to an individual''; and

(C) by inserting before the period at the end ''notwithstanding the applicability of the SAFETY Act (6 U.S.C. 441 et seq.)'';

(4) in subsection (p)(2)—

(A) in the heading, by striking ''COUNTERMEASURE AGAINST SMALLPOX'' and inserting ''COVERED COUNTERMEASURES'';

(B) in subparagraph (A)(i)—

(i) by inserting ''(I)'' after ''makes advisable''; and

(ii) by inserting before the period at the end ''; or (II) the manufacture or distribution of a covered countermeasure for possible future administration to a category or categories of individuals'';

(C) in subparagraph (A)(ii) by inserting—

(i) '', or product or products'' after ''or substances''; and

(ii) before the period at the end ''and any conditions governing the manufacture or distribution of such covered countermeasures'';

(D) in subparagraph (A)(iv), by adding at the end before the period ''. Notwithstanding clause (iii), such declaration or amendment shall take effect immediately upon publication and shall not be subject to the provisions of section 553 of title 5, United States code, con-

cerning prior notice and opportunity for comment''.

(E) in subparagraph (A), by adding at the end the following:

''(v) RECOMMENDED DECLARATION.—Any person may recommend to the Secretary at any time the declaration of a countermeasure under this paragraph and may provide data and information to support such recommendation.'';

(F) in subparagraph (B)(i), by striking '', for a purpose stated in paragraph (7)(A)(i),''; and

(G) by adding at the end the following:

''(E) LIABILITY OF THE UNITED STATES.—The United States shall be liable under this subsection with respect to a claim arising out of the manufacture, distribution, or administration of a covered countermeasure regardless of whether—

''(i) the cause of action seeking compensation for harm caused by such countermeasure is alleged as negligence, strict liability, breach of warranty, failure to warn, or other action; or

"(ii) the covered countermeasure is designated or certified as a qualified anti-terrorism technology under the SAFETY Act (6 U.S.C. 441 et seq.).

The United States shall be liable under this subsection for claims for injury or loss arising out of administration of a covered countermeausre during a human clinical investigation on a covered countermeasure whether or not the certification for successful development of the countermeausre is made under section 301(b)(3) of the Project BioShield II Act of 2005.

"(F) LIABILITY OF THE UNITED STATES FOR MANUFACTURE OR DISTRIBUTION WITHIN THE SCOPE OF DECLARATION.—

"(i) IN GENERAL.—Except as provided in paragraph (5)(B)(ii), the United States shall be liable under this subsection with respect to a claim arising out of the manufacture or distribution of a covered countermeasure if—

"(I) the manufacturer was covered by a declaration by the Secretary

under subparagraph (A) with respect to such countermeasure; and

''(II) the countermeasure was manufactured and distributed in accordance with, and during, the relevant period of such declaration.

''(ii) EFFECT OF SECTION.—For purposes of this section, any activity reasonably related to the manufacture, distribution, or administration of a covered countermeasure shall be considered to be a medical, surgical, dental, or related function within the scope of the covered person's employment by the Public Health Service.'';

(5) in subsection (p)(4)(A), by inserting ''manufacture, distribution, or'' after ''arising out of the''; and

(6) in subsection (p)(7)—

(A) by striking subparagraph (A) and inserting the following:

''(A) COVERED COUNTERMEASURE.—

''(i) BEFORE PUBLICATION OF LIST.—Until the date that the Secretary publishes the list described under section

319F–3(f), the term ''covered countermeasure'' means a substance or product that is specified in a declaration under paragraph (2).

''(ii) After publication of list. After the date that the Secretary publishes the list described under section 319F–3(f), the term ''covered countermeasure'' means a substance or product that is—

''(I) specified in a declaration under paragraph (2); and

''(II)(aa) a countermeasure, as such term is defined is section 319F–3; or

''(bb) designed, developed, modified, used, or procured for the purpose of preventing, detecting, identifying, or treating pandemic influenza or limiting the harm such influenza might otherwise cause.'';

(B) in subparagraph (B)—

(i) in the matter preceding clause (i), by inserting ''manufacture, distribution, or'' after ''with respect to the''; and

(ii) in clause (iv), by inserting ''or distribution'' after ''with respect to administration''; and

(C) in subparagraph (D)—

(i) in the heading, by inserting ''MANUFACTURE, DISTRIBUTION, OR'' after ''ARISING OUT OF'';

(ii) in the matter preceding clause (i) by—

(I) striking ''administration of a covered countermeasure''; and

(II) by inserting ''relating to the manufacture, distribution, or administration of a covered countermeasure'' after ''with respect to a claim or liability'';

(iii) in clause (iii), by striking ''; or'' and inserting a semicolon;

(iv) in clause (iv) by striking the period and inserting ''; or''; and

(v) by adding at the end the following:

''(v) the manufacture or distribution of a covered countermeasure and administration of a covered countermeasure in the course of a human clinical investigation.

For purposes of this subsection, the term 'administration' includes administration in the course of a human clinical investigation.''.

(b) AMENDMENTS TO THE SAFETY ACT.—The SAFETY Act (6 U.S.C. 441 et seq.) is amended—

(1) in section 863, in subsections (a)(1), (a)(2), (d)(1), and (d)(2), by inserting '', or potential threat of such act,'' after ''from such act'';

(2) in section 864—

(A) in subsections (a)(1), (b), and (c), by inserting ''or potential threat of such act'' after ''from such act''; and

(B) in subsection (a)(3), by inserting ''or potential threat of such act'' after ''act of terrorism''; and

(3) in section 865(1)—

(A) by inserting ''(including a vaccine, therapeutic or other biological product, drug, antimicrobial or combination thereof, detection technology, or device)'' after ''product'';

(B) by inserting '', biotechnology, detection technology, or a pharmacological product'' after ''information technology''; and

(C) by inserting ''treating,'' after ''preventing,''.

(c) LIMITATION.—A private entity may utilize the liability protections described in this section (and the amendments made by this section) if such entity—

(1)(A) is described under section 301(b)(2); and

(B) has been certified by the Secretary of Health and Human Services or the Secretary of Homeland Security, as appropriate, under section 301(b)(4); or

(2) without regard to the requirements of sections 301(b)(2) and 301(b)(4), has developed a product (including a drug, vaccine, or other biologic), equipment, service (including support service), device, or technology (including information technology) designed, developed, modified, used, or procured for the specific purpose of preventing, detecting, identifying, or treating pandemic influenza or limiting the harm such pandemic might cause.

(d) EFFECT OF SECTION.—Notwithstanding any other provision of law, an entity shall not be required to apply for and receive designation or certification by the Secretary of Homeland Security of a product or service as a Qualified Anti-Terror Technology under the SAFE-

TY Act (6 U.S.C. 441 et seq.) in order to receive indemnification under Public Law 85–804.

(e) EFFECT ON PENDING ACTIONS.—Nothing in this Act (or the amendments made by this Act) shall be construed to apply to a legal action pending or filed on or before the date of enactment of this Act against a manufacturer or other entity with respect to a diagnostic, therapeutic, detection technology, or research that was not conducted pursuant to a contract under the amendments made by this Act or the Project BioShield Act of 2004 (Public Law 108–276).

TITLE IV—VALLEY OF DEATH FOR SMALL COMPANIES

SEC. 401. PURPOSE.

It is the purpose of this title to enable small companies to fund the initial research and development necessary so that such small companies may be able to participate in the procurement process for countermeasures, and become part of a national biodefense, infectious disease, and research tool industry.

SEC. 402. VALLEY OF DEATH FOR SMALL COMPANIES.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b), as amended by section 103, is amended by—

(1) redesignating subsections (l) and (m) as subsections (r) and (s), respectively; and

(2) inserting after subsection (k) the following:

''(l) REIMBURSEMENT.—The Secretary may reimburse an entity for costs associated with improvement, increase, or production of a countermeasure necessary for testing (including a clinical trial) conducted on humans or animals from funds appropriated to fund the Project BioShield Act of 2004 and the Project BioShield II Act of 2005.

''(m) GRANTS TO CERTAIN ENTITIES.—The Secretary may award grants to State or local government agencies, small businesses, university technology partnership offices, and other entities to conduct preliminary screening of compounds and to develop of business plans related to such preliminary screenings.

''(n) SECURITY FUNDING.—The Secretary shall provide funding for an entity that enters into an agreement under the amendments made by the Project BioShield Act of 2004 or the Project BioShield II Act of 2005 (and the amendments made by such Act) to provide security for the personnel and facilities of such entity that develop, produce, distribute, or store countermeasures under section 319K.

''(o) PRIORITY ACCESS TO CERTAIN RESEARCH RESULTS.—An entity that enters into an agreement under this section, section 319F–2, or section 512 of the Homeland Security Act of 2002 shall be given priority access to the results of research related to the epidemiology and pathogenesis of agents, the genomes and other DNA analysis, or other comparative analysis of agents relevant to research conducted under subparagraphs (A), (B), and (C) of section 319F(h)(1).

''(p) TRANSLATIONAL DEVELOPMENT FOR BIODEFENSE DRUG AND VACCINE CANDIDATES.—

''(1) IN GENERAL.—An entity that enters into an agreement under this section, section 319F–2, or section 512 of the Homeland Security Act of 2002 shall be eligible for translational development for biodefense drug and infectious disease countermeasure candidates. For purposes of this section, such entities may include universities, small businesses, for-profit, and nonprofit entities.

''(2) TRANSLATIONAL DEVELOPMENT.—In this subsection, the term 'translational development' shall include the following:

''(A) Triage screening of applications for promising drug and biological candidates.

''(B) Plans to outline the tasks, timelines, and costs required to complete the development process for promising drug and biological candidates.

''(C) Implementation of the recommended development steps for key therapeutics.

''(D) Project management to implement the recommended development steps.

''(E) Regulatory consultants to interface with the Food and Drug Administration and the entity to devise a plan that rapidly brings new biodefense candidates to approval and stockpiling.

''(q) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary or the Secretary of Homeland Security to distribute countermeasures from the Strategic National Stockpile to foreign countries or foreign entities if it is determined by such Secretaries that such a deployment would protect the interests and safety of citizens of the United States, living in the United States or abroad, from the event of a bioterrorist attack or other public health emergency.''.

TITLE V—BIOSHIELD ANTITRUST EXEMPTION

SEC. 501. LIMITED ANTITRUST EXEMPTION.

Section 2 of the Clayton Act (15 U.S.C. 13) is amended by adding at the end the following:

''(g) LIMITED ANTITRUST EXEMPTION.—

''(1) COUNTERMEASURES DEVELOPMENT MEETINGS.—

''(A) COUNTERMEASURES DEVELOPMENT MEETINGS AND CONSULTATIONS.—The Secretary may conduct meetings and consultations with parties involved in the development of countermeasures for the purpose of the development, manufacture, distribution, purchase, or sale of countermeasures consistent with the purposes of this title. The Secretary shall give notice of such meetings and consultations to the Attorney General and the Chairperson of the Federal Trade Commission (referred to in this subsection as the 'Chairperson').

''(B) MEETING AND CONSULTATION CONDITIONS.—A meeting or consultation conducted under subparagraph (A) shall—

''(i) be chaired or, in the case of a consultation, facilitated by the Secretary;

"(ii) be open to parties involved in the development, manufacture, distribution, purchase, or sale of countermeasures, as determined by the Secretary;

"(iii) be open to the Attorney General and the Chairperson;

"(iv) be limited to discussions involving the development, manufacture, distribution, or sale of countermeasures, consistent with the purposes of this title; and

"(v) be conducted in such manner as to ensure that national security, confidential, and proprietary information is not disclosed outside the meeting or consultation.

"(C) MINUTES.—The Secretary shall maintain minutes of meetings and consultations under this subsection, which shall not be disclosed under section 552 of title 5, United States Code.

"(D) EXEMPTION.—The antitrust laws shall not apply to meetings and consultations under this paragraph, except that any agreement or conduct that results from a meeting or consultation and that does not receive an ex-

emption pursuant to this subsection shall be subject to the antitrust laws.

''(2) WRITTEN AGREEMENTS.—The Secretary shall file a written agreement regarding covered activities, made pursuant to meetings or consultations conducted under paragraph (1) and that is consistent with this paragraph, with the Attorney General and the Chairperson for a determination of the compliance of such agreement with antitrust laws. In addition to the proposed agreement itself, any such filing shall include—

''(A) an explanation of the intended purpose of the agreement;

''(B) a specific statement of the substance of the agreement;

''(C) a description of the methods that will be utilized to achieve the objectives of the agreement;

''(D) an explanation of the necessity of a cooperative effort among the particular participating parties to achieve the objectives of the agreement; and

''(E) any other relevant information determined necessary by the Secretary in consulta-

tion with the Attorney General and the Chairperson.

''(3) DETERMINATION.—The Attorney General, in consultation with the Chairperson, shall determine whether an agreement regarding covered activities referred to in paragraph (2) would likely—

''(A) be in compliance with the antitrust laws, and so inform the Secretary and the participating parties; or

''(B) violate the antitrust laws, in which case, the filing shall be deemed to be a request for an exemption from the antitrust laws, limited to the performance of the agreement consistent with the purposes of this title.

''(4) ACTION ON REQUEST FOR EXEMPTION.—

''(A) IN GENERAL.—The Attorney General, in consultation with the Chairperson, shall grant, deny, grant in part and deny in part, or propose modifications to a request for exemption from the antitrust laws under paragraph (3) within 15 days of the receipt of such request.

''(B) EXTENSION.—The Attorney General may extend the 15-day period referred to in subparagraph (A) for an additional period of

not to exceed 10 days. Such additional period may be further extended only by the United States district court, upon an application by the Attorney General after notice to the Secretary and the parties involved.

''(C) DETERMINATION.—In granting an exemption under this paragraph, the Attorney General, in consultation with the Chairperson and the Secretary—

''(i) must find—

''(I) that the agreement involved is necessary to ensure the availability of countermeasures;

''(II) that the exemption from the antitrust laws would promote the public interest; and

''(III) that there is no substantial competitive impact to areas not directly related to the purposes of the agreement; and

''(ii) may consider any other factors determined relevant by the Attorney General and the Chairperson.

''(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption granted under paragraph (4)

shall be limited to covered activities, and shall expire on the date that is 3 years after the date on which the exemption becomes effective (and at 3-year intervals thereafter, if renewed) unless the Attorney General in consultation with the Chairperson determines that the exemption should be renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

''(6) LIMITATION ON PARTIES.—The use of any information acquired under an exempted agreement by the parties to such an agreement for any purposes other than those specified in the antitrust exemption granted by the Attorney General shall be subject to the antitrust laws and any other applicable laws.

''(7) GUIDELINES.—The Attorney General and the Chairperson may develop and issue guidelines to implement this subsection.

''(8) REPORT.—Not later than 1 year after the date of enactment of the Project BioShield II Act of 2005, and annually thereafter, the Attorney General and the Chairperson shall report to Congress on the use and continuing need for the exemption from the antitrust laws provided by this subsection.

''(9) SUNSET.—The authority of the Attorney General to grant or renew a limited antitrust exemption under this subsection shall expire at the end of the 10-year period that begins on the date of enactment of the Project BioShield II Act of 2005.

''(h) DEFINITIONS.—In this section:

''(1) ANTITRUST LAWS.—The term 'antitrust laws'—

''(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes the Act of June 19, 1936 (15 U.S.C. 13 et seq.) commonly known as the Robinson-Patman Act), and section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition; and

''(B) includes any State law similar to the laws referred to in subparagraph (A).

''(2) COUNTERMEASURE.—The term 'countermeasure' has the meaning given that term in section 319F–3 of the Public Health Service Act.

''(3) COVERED ACTIVITIES.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered activities'

means any group of activities or conduct, including attempting to make, making, or performing a contract or agreement or engaging in other conduct, for the purpose of—

''(i) theoretical analysis, experimentation, or the systematic study of phenomena or observable facts necessary to the development of countermeasures;

''(ii) the development or testing of basic engineering techniques necessary to the development of countermeasures;

''(iii) the extension of investigative findings or theory of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, prototypes, equipment, materials, and processes necessary to the development of countermeasures;

''(iv) the production, distribution, or marketing of a product, process, or service that is a countermeasures;

''(v) the testing in connection with the production of a product, process, or serv-

ices necessary to the development of countermeasures;

''(vi) the collection, exchange, and analysis of research or production information necessary to the development of countermeasures; or

''(vii) any combination of the purposes described in clauses (i) through (vi);

and such term may include the establishment and operation of facilities for the conduct of covered activities described in clauses (i) through (vi), the conduct of such covered activities on a protracted and proprietary basis, and the processing of applications for patents and the granting of licenses for the results of such covered activities.

''(B) EXCEPTION.—The term 'covered activities' shall not include the following activities involving 2 or more persons:

''(i) Exchanging information among competitors relating to costs, sales, profitability, prices, marketing, or distribution of any product, process, or service if such information is not reasonably necessary to

carry out the purposes of covered activities.

''(ii) Entering into any agreement or engaging in any other conduct—

''(I) to restrict or require the sale, licensing, or sharing of inventions, developments, products, processes, or services not developed through, produced by, or distributed or sold through such covered activities; or

''(II) to restrict or require participation by any person who is a party to such covered activities in other research and development activities, that is not reasonably necessary to prevent the misappropriation of proprietary information contributed by any person who is a party to such covered activities or of the results of such covered activities.

''(iii) Entering into any agreement or engaging in any other conduct allocating a market with a competitor that is not ex-

pressly exempted from the antitrust laws by a determination under subsection (i)(4).

''(iv) Exchanging information among competitors relating to production (other than production by such covered activities) of a product, process, or service if such information is not reasonably necessary to carry out the purpose of such covered activities.

''(v) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production of a product, process, or service that is not so expressly exempted from the antitrust laws by a determination under subsection (i)(4).

''(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in any other conduct to restrict or require participation by any person who is a party to such activities, in any unilateral or joint activity that is not reasonably necessary to carry out the purpose of such covered activities.

''(4) DEVELOPMENT.—The term 'development' includes the identification of suitable compounds or biological materials, the conduct of preclinical and clinical studies, the preparation of an application for marketing approval, and any other actions related to preparation of a countermeasure.

''(5) PERSON.—The term 'person' has the meaning given such term in subsection (a) of the first section of this Act.

''(6) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services.''.

TITLE VI—BIOSHIELD IMMIGRATION PRIORITY

SEC. 601. H1B VISA EXEMPTION.

Section 214(g) of the Immigration and Nationality Act (8 U.S.C. 1184(g)) is amended by adding at the end the following new paragraph:

''(9)(A) The numerical limitations contained in paragraph (1)(A) shall not apply to any nonimmigrant alien issued a visa or otherwise provided status under section 101(a)(15)(H)(i)(b) who—

''(i) is employed by a person that has entered into a contract for procurement with the Secretary of Health and Human Services under the authority provided in section 319F–1 or 319F–2 of the Public

Health Service Act (42 U.S.C. 247d–6a and 247d–6b) or with the Secretary of Homeland Security under section 512 of the Homeland Security Act of 2002; and

''(ii) provides services related to the research, development, or production of a qualified countermeasure or a security countermeasure under such contract.

''(B) In this paragraph:

''(i) The term 'qualified countermeasure' has the meaning given that term in section 319F–1 of the Public Health Service Act.

''(ii) The term 'security countermeasure' has the meaning given that term in section 319F–2 of the Public Health Service Act.''.

SEC. 602. VISA PROCESSING.

(a) REQUIREMENT TO EXPEDITE.—The Secretary of Homeland Security and the Secretary of State shall expedite the processing of an application of an alien seeking a visa under section 101(a)(15)(H)(i)(b) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(15)(H)(i)(b)) if such alien—

(1) is employed by a person that has entered into a contract for procurement with the Secretary of Health and Human Services under the authority

provided in section 319F–1 or 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a and 247d–6b) or with the Secretary of Homeland Security under section 512 of the Homeland Security Act of 2002; and

(2) provides services related to the research, development, or production of a qualified countermeasure or a security countermeasure under such contract.

(b) DEFINITIONS.—In this section:

(1) QUALIFIED COUNTERMEASURE.—The term ''qualified countermeasure'' has the meaning given that term in section 319F–1 of the Public Health Service Act.

(2) SECURITY COUNTERMEASURE.—The term ''security countermeasure'' has the meaning given that term in section 319F–2 of the Public Health Service Act.

TITLE VII—BIOSHIELD EXPORT PRIORITY

SEC. 701. SHORT TITLE.

This title may be cited as the ''Bioshield Export Priority Act''.

SEC. 702. REQUIREMENT TO EXPEDITE EXPORT APPLICATIONS.

(a) IN GENERAL.—The Secretary of Commerce or the Secretary of Health and Human Services, whichever is applicable, shall expedite the processing of a request to export a drug, medical device, diagnostic test, etiological agent, biological product, or any item the export of which is restricted pursuant to section 5 or 6 of the Export Administration Act of 1979 (as in effect pursuant to the International Emergency Economic Powers Act; 50 U.S.C. 1701 et seq.), if the export of that drug, medical device, diagnostic test, etiological agent, biological product, or other item is necessary to carry out a procurement contract entered into by the Secretary of Health and Human Services under the authority provided in section 319F–1 or section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a and 247d–6b), or by the Secretary of Homeland Security under section 512 of the Homeland Security Act of 2002, with respect to a qualified countermeasure or security countermeasure under such contract.

(b) QUALIFIED AND SECURITY COUNTERMEASURES DEFINED.—In this section:

(1) the term ''qualified countermeasure'' has the meaning given that term in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a); and

(2) the term ''security countermeasure'' has the meaning given that term in section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b).

SEC. 703. PRESERVATION OF FOREIGN SALES MARKETS FOR QUALIFIED AND SECURITY COUNTERMEASURES.

Notwithstanding any other provision of law, no Federal agency shall sell, barter, trade, or transfer a qualified countermeasure or a security countermeasure to a foreign government, or to any other foreign entity or purchaser outside the United States where an entity that has successfully developed a countermeasure under this Act or the Project BioShield Act of 2004 (Public Law 108–276) (and the amendments made by such Acts) is able to sell, barter, trade, or transfer such countermeasure to such foreign government or entity, unless the President makes a determination that such sale, barter, trade, or transfer is necessary for protecting the national security or national defense of the United States.

TITLE VIII—OFFICE OF PUBLIC HEALTH COUNTERMEASURE DEVELOPMENT

SEC. 801. OFFICE OF PUBLIC HEALTH COUNTERMEASURE DEVELOPMENT.

Section 2811(a) of the Public Health Service Act (42 U.S.C. 300hh–11(a)) is amended to read as follows:

''(a) ASSISTANT SECRETARY FOR PUBLIC HEALTH COUNTERMEASURE DEVELOPMENT.—

''(1) IN GENERAL.—There is established within the Department of Health and Human Services the Office of Public Health Countermeasure Development (referred to in this subsection as the 'Office'). Such Office shall be headed by an Assistant Secretary for Public Health Countermeasure Development, who shall be appointed by the President and shall report to the Secretary.

''(2) DEPUTY DIRECTOR.—There is established within the Department of Health and Human Services the position of Deputy Director for Medical Countermeasure Development.

''(3) DUTIES.—The Assistant Secretary for Public Health Countermeasure Development shall ensure that research supported by the Department of Health and Human Services—

"(A) is consistent with the national preparedness plan developed under section 2812 with respect to—

"(i) identifying priorities, goals, objectives, and policies for identifying, developing, delivering, and evaluating medical and other countermeasures to biological, chemical, radiological, nuclear, and other emerging natural and terrorists threats and infectious diseases and research tools and countermeasures should include containment and decontamination strategies for human and animal remains; and

"(ii) coordinating the civilian efforts of the Federal Government to identify and rapidly develop such countermeasures; and

"(B) is conducted pursuant to a comprehensive, research-based strategy for—

"(i) the conduct of basic and applied research;

"(ii) the development of the countermeasures described under subparagraph (A)(i); and

''(iii) the development of standards by which the goals of such strategy may be accomplished and evaluated.''.

SEC. 802. BIOTERROR, CHEMICAL, NUCLEAR, RADIOLOGICAL, AND INFECTIOUS DISEASE COUNTERMEASURE DEVELOPMENT STRATEGY.

Subtitle B of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–11 et seq.) is amended by adding at the end the following:

''SEC. 2812. BIOTERROR, CHEMICAL, NUCLEAR, RADIOLOGICAL, AND INFECTIOUS DISEASE COUNTERMEASURE DEVELOPMENT STRATEGY.

''(a) PLAN FOR COUNTERMEASURE RESEARCH.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Defense and the Secretary of Homeland Security, shall develop a comprehensive, long-term plan for engaging State and local public health officials, medical examiners, and other non-Federal entities, including private for-profit entities, in the research, development, production, delivery, and evaluation of countermeasures for biological, chemical, radiological, and nuclear weapons and infectious diseases.

''(2) CONTENTS.—The plan described under paragraph (1) shall include a plan for the develop-

ment of countermeasures for exotic pathogens (including vaccine resistant bacterial or viral strains, antibiotic resistant organisms, genetically modified organisms, hybrid organisms, synthetic organisms, autoimmune peptides, antibiotic-induced toxins, ethnic and racial specific pathogens, and bioregulators and biomodulators) and measures for containment and safe handling of contaminated human and animal remains.

''(3) OTHER DUTIES.—The Secretary, in consultation with the Secretary of Defense and the Secretary of Homeland Security, shall—

''(A) develop a plan and strategy for engaging pharmaceutical and biotechnology companies, universities, small businesses, and nonprofit institutions, including entities that are under-resourced and not able to advance beyond preclinical development to clinical trials, in order to create a multi-dimensional biodefense, infectious disease, vaccine, and research tool industry; and

''(B) provide joint oversight of translational development for biodefense drug and vaccine candidates, as provided in section 319F–2(o).

"(4) COORDINATION; PURPOSE.—In developing the plan described under paragraph (1), the Secretary, in consultation with the Secretary of Defense and the Secretary of Homeland Security, shall—

"(A) consult with—

"(i) other Federal agencies with expertise in research, development, and production of the countermeasures described under paragraph (1);

"(ii) private, for-profit entities, State and local public health officials, medical examiners, and entrepreneurs with expertise and technology with respect to such countermeasures, research tools, and the systems for developing such research tools;

"(iii) investors that fund the entities described under clause (ii);

"(iv) nonprofit research universities and institutions;

"(v) professional organizations representing infectious disease physicians and scientists;

"(vi) local public health and hospital organizations; and

"(vii) national and international healthcare delivery and public health entities, and other interested private and public entities;

"(B) evaluate proposals to ensure that—

"(i) Federal efforts assist and incentivize private sector development of systems to facilitate and expedite the development and diffusion of research tools, and research tool systems, to aid in the development and deployment of countermeasures;

"(ii) research and development of such countermeasures by non-Federal entities is likely to yield countermeasures that may be procured and deployed with respect to the homeland security in the United States and against an infectious diseases;

"(iii) ample investor capital is available to fund such research and development, and non-Federal entities are not dependent on grants from the Federal Government;

"(iv) the terms of procurement of such countermeasures are defined in ad-

vance so that entities may accurately and reliably assess—

"(I) the potential countermeasures market;

"(II) the potential rate of return; and

"(III) that the terms of the procurement are comparable to the procurement of other medicines and biological products from other markets;

"(v) appropriate intellectual property, risk protection, and Government approval standards are applicable to such countermeasures;

"(vi) federally funded research is conducted and prioritized to address the highest priority countermeasure detection tools and transfer or license those technologies, as appropriate, to non-Federal entities for production; and

"(vii) universities, State and local government laboratories, and research institutions play a vital role as partners in research, development, and technology transfer, with appropriate progress benchmarks

for such activities, with for-profit entities; and

''(C) provide the private sector with sufficient advance notice of the procurement priorities of the Federal Government with respect to countermeasures.

''(5) PLAN DETAILS.—

''(A) IN GENERAL.—The plan described under paragraph (1) shall, on an annual basis—

''(i) designate, in 5 year increments, specific countermeasures for which contracts under the Project BioShield Act of 2004 and the Project BioShield II Act of 2005 will be awarded;

''(ii) estimate the date on which request for proposals will be published;

''(iii) provide information regarding the qualifications of the entities with which it may enter into an agreement; and

''(iv) list the projected schedule for the completion of the development of such countermeasures.

''(B) DESIGNATION OF COUNTERMEASURES.—

"(i) IN GENERAL.—The plan described in paragraph (1) shall, on an annual basis, designate specific countermeasures to be developed against terror weapons or weapons of mass destruction.

"(ii) INFECTIOUS DISEASE COUNTERMEASURES IN THE UNITED STATES.—For every 5 such countermeasures designated under clause (i), not less than 2 additional countermeasures shall be designated for development against an infectious disease that—

"(I) is not a terror weapon or weapon of mass destruction; and

"(II) has or may have substantial incidence in the United States.

"(iii) GLOBAL INFECTIOUS DISEASE COUNTERMEASURES IN DEVELOPING COUNTRIES.—For every 5 such countermeasures designated under clause (i), not less than 2 additional countermeasures shall be designated for development against an infectious disease that—

"(I) is not a terror weapon or weapon of mass destruction; and

''(II) has or may have substantial incidence largely in developing countries.

''(C) DESIGNATION OF RESEARCH TOOLS; PURCHASE POOLS; ESTIMATION.—The plan described in paragraph (1) shall—

''(i) designate research tools, including research tool systems, to be developed;

''(ii) identify purchase pools with which the Secretary shall seek to negotiate for the development of countermeasures; and

''(iii) estimate the amount of appropriations necessary to procure the development of such countermeasures and research tools.

''(D) PUBLIC AVAILABILITY.—The plan described in paragraph (1) shall be published in the Federal Register.

''(6) PERFORMANCE MEASURE SYSTEM.—

''(A) IN GENERAL.—Not later than 180 days after the development of the plan described in paragraph (1), the Secretary shall implement a performance measure system to evaluate the progress toward the goals of the

Project BioShield II Act of 2005, which shall include a list of clear, measurable benchmarks by which progress may be evaluated, including—

''(i) a list of threats for which countermeasures are necessary;

''(ii) a list of research and research tool systems necessary for the development of countermeasures;

''(iii) systems to develop and deliver countermeasures for at-risk populations;

''(iv) an annual accounting of the number of outbreaks, including incidence numbers and case fatality rates, in the United States of influenza and other such diseases that such Act addresses;

''(v) a list of any new threats that either emerged from nature, or that were engineered and released during the previous year; and

''(vi) an accounting of the time that it took to detect, analyze, and respond to any instance of a threat.

''(B) EVALUATION.—Not later than 1 year after the publication of the benchmarks de-

scribed in subparagraph (A), and on annual basis thereafter, the Secretary shall publish and submit to Congress an evaluation of the progress made with respect to such benchmarks during the preceding year.

''(7) SUBMISSION OF PLAN; REPORTING.—

''(A) SUBMISSION OF PLAN.—Not later than 270 days after the date of enactment of the Project BioShield II Act of 2005, the Secretary shall submit to Congress the plan developed under paragraph (1) and recommendations for the enactment of supporting or enabling legislation with respect to such plan. The Secretary shall submit to Congress an updated version of such plan and such recommendations on an annual basis.

''(B) REPORTING.—The Secretary shall report periodically to Congress on the status of the countermeasure research, development, and production of non-Federal entities, and submit recommendations for legislation as determined necessary by the Secretary.

''(b) ADVISORY COMMITTEE.—

''(1) ESTABLISHMENT OF COMMITTEE.—The Secretary, in consultation with the Secretary of De-

fense and the Secretary of Homeland Security, shall establish an advisory committee to be known as the Public Health Countermeasure Development Advisory Committee (referred to in this section as the 'Advisory Committee').

''(2) DUTIES.—The Advisory Committee shall advise the Secretary, the Secretary of Defense, and the Secretary of Homeland Security with respect to the establishment of a biodefense, an infectious disease, vaccine, and a research tool industry to supply the Federal Government and other public entities with the medical countermeasures necessary to protect the public from biological, chemical, radiological, and nuclear attacks, or infectious diseases.

''(3) MEMBERSHIP.—The Secretary, Secretary of Defense, and the Secretary of Homeland Security shall appoint the members of the Advisory Committee, which shall be composed of—

''(A) representatives of the for-profit and nonprofit research sectors, and State and local governments, including representatives of the small business industry and infectious disease medical, research, biotechnology, and pharmaceutical communities; and

''(B) experts on the terms and impact of the incentives provided under the Project BioShield Act of 2004 or the Project BioShield II Act of 2005 (and the amendments made by such Acts).

''(4) VACANCIES.—Any vacancy in the Advisory Committee shall not affect its powers, but shall be filled in the same manner as the original appointment.

''(5) MEETINGS.—The Advisory Committee shall meet at the call of the co-chairpersons.

''(6) CO-CHAIRPERSONS.—The Secretary, the Secretary of Defense, and the Secretary of Health and Human Services shall serve as the co-chairpersons of the Advisory Committee.

''(7) POWERS.—

''(A) HEARINGS.—The Advisory Committee may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Advisory Committee considers advisable to carry out this section.

''(B) INFORMATION FROM FEDERAL AGENCIES.—

''(i) IN GENERAL.—The Advisory Committee may secure directly from any Federal department or agency such information as the Advisory Committee considers necessary to carry out the provisions of this section. Upon request of the Advisory Committee, the head of such department or agency shall furnish such information to the Advisory Committee.

''(ii) LIMITATION.—Nothing in this subsection shall be construed to allow the Advisory Committee to secure information that is exempt from disclosure under section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act).

''(C) POSTAL SERVICES.—The Advisory Committee may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

''(8) PERSONNEL.—

''(A) TRAVEL EXPENSES.—The members of the Advisory Committee shall not receive compensation for the performance of services

for the Advisory Committee, but shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Advisory Committee. Notwithstanding section 1342 of title 31, United States Code, the Secretary may accept the voluntary and uncompensated services of members of the Advisory Committee.

''(B) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Advisory Committee without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.''.

TITLE IX—OFFICE OF MEDICAL READINESS AND RESPONSE OF THE DEPARTMENT OF HOMELAND SECURITY

SEC. 901. OFFICE OF MEDICAL READINESS AND RESPONSE OF THE DEPARTMENT OF HOMELAND SECURITY.

(a) IN GENERAL.—Title VIII of the Homeland Security Act of 2002 (6 U.S.C. 361 et seq.) is amended by inserting after section 879 the following:

"SEC. 879A. OFFICE OF MEDICAL READINESS AND RESPONSE.

''(a) ESTABLISHMENT.—There is established within the Office of the Secretary an Office of Medical Readiness and Response.

''(b) ASSISTANT SECRETARY.—The Office established under subsection (a) shall be headed by an Assistant Secretary for Medical Readiness and Response, who shall be appointed by the President by and with the advice and consent of the Senate.

''(c) DUTIES OF THE ASSISTANT SECRETARY.—The Assistant Secretary for Medical Readiness and Response shall—

''(1) serve as the principal advisor to the Secretary on all matters related to emergency medical preparedness and response;

''(2) develop Federal strategy, training (including exercises), coordination, funding, and implementation of emergency medical response to mass casualty events for Federal, State, and local public health agencies and private sector entities in support of homeland security;

''(3) serve as the primary Federal official with respect to overseeing the identification and development, in consultation with nonprofit health and public health departments and medical centers, of medical preparedness centers and deployable medical care units designed to meet the demands of a terrorist event or other incident requiring mass casualty care and containment of infectious disease;

''(4) serve as the primary official of the Department relating to and overseeing medical emergencies, including emergencies incident to a terrorist attack or naturally occurring infectious disease outbreak;

''(5) in coordination with the Secretary of Health and Human Services, have the authority to

deploy the Strategic National Stockpile and the Commissioned Corps of the Public Health Service;

''(6) report directly to the Secretary; and

''(7) evaluate and report to Congress on the preparedness of Federal, State, and local agencies to respond to major medical disaster.

''(d) FUNCTIONS.—There shall be transferred to the Office of Medical Readiness and Response the following functions, personnel, assets, and liabilities of the following:

''(1) The National Disaster Medical System (transferred to the Department pursuant to section 503(5)).

''(2) The Metropolitan Medical Response System (transferred to the Department pursuant to section 503(5)).

''(3) The emergency medical response functions of the Office of Emergency Preparedness (transferred to the Department pursuant to section 503(5)).

''(4) Other resources and offices of the Department as designated by the Secretary.''.

(b) CONFORMING AMENDMENTS.—Section 502(3) of the Homeland Security Act of 2002 (6 U.S.C. 312(3)) is amended—

(1) in subparagraph (B)—

(A) by striking ", the National Disaster Medical System,"; and

(B) by striking the semicolon and inserting "; and";

(2) by striking subparagraph (C); and

(3) by redesignating subparagraph (D) as subparagraph (C).

TITLE X—NATIONAL EMERGENCY MEDICAL READINESS AND RESPONSE BOARD

SEC. 1001. NATIONAL EMERGENCY MEDICAL READINESS AND RESPONSE BOARD.

(a) IN GENERAL.—Title VIII of the Homeland Security Act of 2002 (6 U.S.C. 361 et seq.), as amended by section 901, is further amended by inserting after section 879A (as added by section 901) the following:

"SEC. 879B. NATIONAL EMERGENCY MEDICAL READINESS AND RESPONSE BOARD.

"(a) ESTABLISHMENT OF BOARD.—

"(1) IN GENERAL.—There is established in the Department the National Emergency Medical Readiness and Response Board (referred to in this section as the 'Board').

''(2) CHAIRPERSON.—The Assistant Secretary for Medical Readiness and Response shall serve as the chairperson of the Board.

''(3) COMPOSITION.—The Board shall be composed of the following members (or their designees):

''(A) The Assistant Secretary for Medical Readiness and Response.

''(B) The United States Surgeon General.

''(C) The Assistant Secretary for Public Health Countermeasure Development.

''(D) The Director of the National Institutes of Health.

''(E) The Director of the Centers for Disease Control and Prevention.

''(F) The Director of National Bioterrorism and Hospital Readiness of the Health Resources and Services Administration.

''(G) The Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense.

''(H) The Commanding General, Army Medical Research and Materiel Command.

''(I) The Assistant Secretary for Health of the Department of Veterans Affairs.

''(J) The Deputy Commander, United States Northern Command.

''(K) The Commissioner of Food and Drugs.

''(L) The Secretary of Agriculture.

''(M) The Postmaster General.

''(N) Any other individual appointed by the President to the Board.

''(4) MEETINGS.—The Board shall meet at the call of the chairperson.

''(b) DUTIES AND POWERS.—

''(1) DUTIES.—The Board shall oversee the following activities:

''(A) The development, assessment, and validation of national, interagency, emergency medical response plans, in coordination with State and local public health officials, for bioterrorism (including agroterrorism), chemical attack, radiological attack, nuclear attack, infectious disease, and high explosives attack.

''(B) In cooperation with State and local public health agencies, the development, testing, and implementation of a plan for the necessary training related to, and the assessment and

evaluation of, the Federal emergency medical response plans described in subparagraph (A).

"(C) The coordination of the Federal emergency medical response plans described in subparagraph (A) among all the Federal departments and agencies represented on the Board through joint exercises that shall be observed and evaluated by the members of the Board (or their designees).

"(D) Defining, and determining when and how to implement, national level emergency medical response plans to medical disasters.

"(2) POWERS.—The Board may secure directly from any Federal department or agency such information as the Board considers necessary to carry out this subsection. Upon request of the chairperson of the Board, the head of such department or agency shall furnish such information to the Board.

"(c) BOARD PERSONNEL MATTERS.—

"(1) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Board without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

''(2) PROCUREMENT OF TEMPORARY AND INTERMITTENT SERVICES.—The chairperson of the Board may procure temporary and intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals which do not exceed the daily equivalent of the annual rate of basic pay prescribed for level V of the Executive Schedule under section 5316 of such title.

''(d) ADVISORY COMMITTEE.—

''(1) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Project BioShield II Act of 2005, the Assistant Secretary for Medical Readiness and Response shall establish an advisory committee that shall provide assistance and oversight to the Board and to the Assistant Secretary for Medical Readiness and Response.

''(2) COMPOSITION.—The advisory committee established pursuant to paragraph (1) shall consist of representatives, appointed by the Assistant Secretary for Medical Readiness and Response, of—

''(A) designees of State and local public health and emergency management agencies;

''(B) State and local emergency managers or adjutant generals and State emergency medical services directors;

"(C) physicians and first responders (including nurses, police, and paramedics);

"(D) academic medical research institutions;

"(E) the World Health Organization;

"(F) the International Committee of the Red Cross;

"(G) the International Federation of Red Cross and Red Crescent Societies;

"(H) the American Red Cross;

"(I) the Infectious Disease Society of America;

"(J) professional medical and clinical societies, as appropriate;

"(K) local hospitals and hospital districts;

"(L) medical care delivery facilities (hospital outpatient centers);

"(M) pharmacies;

"(N) accredited schools of public health;

"(O) pathologists, coroners, and chief medical examiners; and

"(P) other individuals and representatives of entities appointed by the Assistant Secretary for Medical Readiness and Response to the advisory committee.".

(b) CONFORMING AMENDMENTS.—The table of contents in section 1(b) of the Homeland Security Act of 2002 (6 U.S.C. 101 note) is amended by—

(1) inserting after the item relating to section 511 the following:

"Sec. 510. Countermeasure Purchase Fund at the Department of Homeland Security.";

and

(2) inserting after the item relating to section 879 the following:

"Sec. 879A. Office of Medical Readiness and Response.
"Sec. 879B. National Emergency Medical Readiness and Response Board.".

TITLE XI—ENCOURAGING GREATER COORDINATION WITH FORMER SOVIET SCIENTISTS AND TRANSFER OF COUNTERMEASURES

SEC. 1101. PURPOSE; REPORT TO CONGRESS.

(a) PURPOSE.—The purpose of this section is to direct the Department of State and the Department of Commerce to develop and implement a program to secure the access to, and transfer of, compounds, culture collections, devices, scientific methods, and research tools to the United States to further the protection of the United States and its allies against biological, chemical, nuclear, and radiological agents or infectious diseases. Such an ef-

fort must address the state of intellectual property of such items and ensure the security of such intellectual property to allow for and encourage commercialization.

(b) REPORT.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of the Project BioShield II Act of 2005, the Secretary of State, in cooperation with the Secretary of Homeland Security and Secretary of Commerce, shall report to the Committee on Foreign Relations of the Senate and the Committee on International Relations of the House of Representatives on the existence and adequacy of all United States Government-sponsored programs or organizations responsible for encouraging commercialization of countermeasures developed by former-Soviet scientists and current scientists working within the Commonwealth of Independent States (referred to in this section as ''CIS'').

(2) CONTENT OF REPORT.—The report described under paragraph (1) shall identify any known legal prohibitions and practical challenges in the United States or CIS to the purposes of this section, including laws governing intellectual property, export controls, and classification of information restricting or inhibiting private-sector exchange and

development of such countermeasures. The Secretary of State shall provide such information as the Secretary determines to be necessary to enable such potential commercialization and cooperation.

TITLE XII—EMERGENCY CONTINUITY OF NATIONAL HEALTHCARE; REIMBURSEMENT OF INFECTIOUS DISEASE PHYSICIANS FOR COMMUNITY EMERGENCY PREPAREDNESS ACTIVITIES; MEDICAL LICENSE RECIPROCITY

SEC. 1201. CONTINUITY OF NATIONAL HEALTHCARE SYSTEM IN AN EMERGENCY.

Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

''(e) CONTINUITY OF NATIONAL HEALTHCARE SYSTEM IN AN EMERGENCY.—

''(1) EMERGENCY HEALTH INSURANCE REIMBURSEMENT.—In the event of a public health emergency determined pursuant to subsection (a), the Secretary may guarantee reimbursement to public and private healthcare providers (which shall include

nurses and non-clinical staff) for care related to the public health emergency provided to individuals by such providers to the extent that the public or private health insurance reimbursement (as the case may be) to such providers is not applicable because of war or terrorism coverage exclusions at one of the following rates:

"(A) The applicable rates under the Medicare and Medicaid programs.

"(B) A per diem rate determined by the Secretary.

"(2) GUARANTEE OF PAYMENTS.—During a closure of the United States mails due to a public health emergency determined pursuant to subsection (a), the Secretary may provide a guarantee of payment to private healthcare providers to enable such providers to maintain services and continuity in response to such emergency.".

SEC. 1202. REIMBURSEMENT OF INFECTIOUS DISEASE PHYSICIANS FOR COMMUNITY EMERGENCY PREPAREDNESS ACTIVITIES.

Section 319 of the Public Health Service Act (as amended by section 1201) is further amended by adding at the end the following:

''(f) REIMBURSEMENT OF INFECTIOUS DISEASE PHYSICIANS FOR COMMUNITY EMERGENCY PREPAREDNESS ACTIVITIES.—The Secretary shall reimburse board-certified infectious disease and public health specialists for services provided during a public health emergency under subsection (a) at applicable rates under the Medicare program, to the extent that such services are not otherwise wholly reimbursed by other public or private insurance.''.

SEC. 1203. MEDICAL LICENSE RECIPROCITY.

Section 319 of the Public Health Service Act (42 U.S.C. 247d) (as amended by section 1202) is further amended by adding at the end the following:

''(g) MEDICAL LICENSE RECIPROCITY.—The Secretary may issue regulations requiring the establishment of reciprocity of medical licensing and certification between or among States during a national or local public health emergency determined pursuant to subsection (a).

''(h) MINIMUM STANDARDS.—Medical licensing for the purposes of subsection (g) shall include the licensing of allopathic and osteopathic physicians, registered nurses, nurse practitioners, physician assistants, pharmacists, paramedics, respiratory therapists, and other first responders or allied health professionals.

''(i) PSA.—The Secretary may issue regulations requiring or providing appropriate liability and workman's

compensation coverage for healthcare professionals and others responding to a public health emergency, as determined under subsection (a).''.

SEC. 1204. LIABILITY PROTECTION FOR HEALTHCARE VOLUNTEERS AND HOSPITALS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) (as amended by sections 202, 1402, 1631, 1901, 2101, 2102, and 1631) is amended by inserting after section 319F–9 (as added by section 203) the following:

''SEC. 319F–10. LIABILITY PROTECTION FOR HEALTHCARE VOLUNTEERS AND HOSPITALS LITIGATION MANAGEMENT.

''(a) FEDERAL CAUSE OF ACTION.—

''(1) IN GENERAL.—There shall exist an exclusive Federal cause of action for claims arising out of, related to, or resulting from care delivered by any person or entity at any location in the United States if the governor of that State has declared a state of emergency, or the Secretary of Health and Human Services declares that a public health emergency is in effect in that State, or the President signs a disaster declaration for that State. Such Federal cause of action shall be brought in the United States district court for the District of Columbia and shall be

only for injuries that are caused by willful or wanton misconduct.

''(2) LIMITATIONS.—Healthcare personnel, volunteers, and other workers providing emergency medical or triage care in field settings, alternative treatment facilities, and in vaccination or medication distribution settings shall be immune from claim for loss of property (including business interruption or other types of indirect losses), personal injury, or death.

''(b) SPECIAL RULES.—

''(1) IN GENERAL.—When a hospital is providing care under emergency conditions as described in this section and such care is not administered for or in expectation of compensation, then the maximum liability to the Federal Government on behalf of the hospital (or its employees, volunteers, officers, and directors) is $250,000 for each claimant.

''(2) PUNITIVE DAMAGES.—No punitive damages intended to punish or deter, exemplary damages, or other damages not intended to compensate a plaintiff for actual medical expenses or lost wages may be awarded in an action under this section, nor shall any party in such action be liable for interest prior to the judgment.

''(3) NONECONOMIC DAMAGES.—No non-economic damages may be awarded for claims under this section.

''(4) LIMITATIONS.—Hospitals and other health care organizations shall be immune from vicarious liability for the actions of volunteers providing care under emergency conditions described in this section, even if the hospital or health care organization is considered the employer for worker' compensation purposes.

''(5) ATTORNEY FEES.—Attorney fees in an action under this section shall be calculated on a reasonable amount of work performed on behalf of the plaintiff.''.

TITLE XIII—ADEQUACY OF EMERGENCY MEDICAL RESPONSE ASSETS FOR HOMELAND SECURITY MISSIONS

SEC. 1301. ADEQUACY OF EMERGENCY MEDICAL RESPONSE ASSETS FOR HOMELAND SECURITY MISSIONS.

(a) STUDY.—The Assistant Secretary for Medical Readiness and Response of the Department of Homeland Security shall perform a study and prepare a report assessing the state of medical and health readiness and re-

sponse capability to respond to large-scale medical emergencies, such as terrorist actions. The study will evaluate the following aspects of medical and health readiness and response:

(1) The nature and extent of emergency medical and health resources needed to respond to and mitigate a biological, chemical, radiological, or nuclear attack or an infectious disease outbreak.

(2) The assets and resources currently available from the Federal, State, and local governments, private sector entities, industry, hospitals, and academia to meet the homeland security mission.

(3) The deficiencies in assets and resources needed to respond to such an attack or outbreak.

(4) Recommendations regarding the types and extent of assets and resources needed to be secured to respond to such an attack or outbreak, including those requested from State and local public health agencies and their volunteer responders.

(b) CONTENT.—The report described in subsection (a) shall assess and make recommendations with regard to—

(1) the appropriate roles and responsibilities in responding to a medical emergency of—

(A) full-time government employees;

(B) part-time personnel; and

(C) volunteer personnel;

(2) the appropriate skills and skilled workers needed, including physicians (including infectious diseases specialists), other health care personnel, and first responders;

(3) the appropriate planning and training needed prior to an attack or outbreak;

(4) the appropriate contingency plans for responding to a novel or catastrophic incident; and

(5) mechanisms to—

(A) develop and pilot test strategies to be used to reduce disease transmission in a bioterrorism incident, a public health emergency, or an epidemic or pandemic;

(B) develop and validate meaningful national standards for Federal, State, and local public health agencies and for nongovernmental healthcare delivery institutions in preparedness for and response to epidemics, pandemics, and mass casualty incidents;

(C) test these methods in State, local, and multi-State proof-of-concept tests; and

(D) develop public risk communication tools that support the widespread use of such activities.

(c) CONSULTATION.—In preparing this report, the Assistant Secretary for Medical Readiness and Response of the Department of Homeland Security shall consult with the members of the National Emergency Preparedness and Response Board.

(d) SUBMISSION DATE.—The report shall be submitted to Congress not later than 1 year after the date of enactment of this Act.

TITLE XIV—CONSTRUCTION OF SPECIALIZED RESEARCH FACILITIES FOR THE DEVELOPMENT OF COUNTERMEASURES

SEC. 1401. CONSTRUCTION OF SPECIALIZED RESEARCH FACILITIES FOR THE DEVELOPMENT OF COUNTERMEASURES.

(a) IN GENERAL.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) (as amended by sections 202, 1901, 2101, and 2102) is amended by inserting after section 319F–6 (as added by section 2102) the following:

"SEC. 319F–7. CONSTRUCTION OF BIOSAFETY LEVEL 3–4 RESEARCH FACILITIES.

''(a) FINDINGS.—Congress finds that—

''(1) research to develop countermeasures requires the use of special facilities where biological and chemical agents can be handled safely both for laboratory research and efficacy testing in animal models;

''(2) very few companies and very few State and local public health laboratories have sufficient funds for the construction of these special facilities; and

''(3) the Federal Government can facilitate research and development of countermeasures by financing the construction of these special facilities.

''(b) GRANTS AUTHORIZED.—

''(1) IN GENERAL.—The Secretary is authorized to award grants and contracts to grantees to construct, maintain, and manage (including funding for staff and staff training) biosafety level 3–4 facilities.

''(2) REQUIREMENTS.—To be eligible for a grant under paragraph (1) an entity shall—

''(A) allow use of the facility involved by only those researchers who meet qualifications set by the Secretary;

''(B) give priority for the use of the facility involved to those entities that have been reg-

istered and certified by the Secretary to develop countermeasures; and

''(C) allow the National Institutes of Health and the Centers for Disease Control and Prevention to inspect the facility involved at any time.

''(3) NUMBER OF GRANTS.—The Secretary of Homeland Security shall determine the number of facilities that need to be constructed under this section, not to exceed 10 such facilities nationwide, and the Secretary shall award grants based on such determination.

''(c) APPLICATION.—

''(1) IN GENERAL.—To be eligible to receive a grant under this section, an entity shall submit to the Secretary an application at such time, in such form, and containing such information as the Secretary may require.

''(2) CONTENTS.—Each application submitted pursuant to paragraph (1) shall—

''(A) provide detailed information on the technical specifications of proposed facilities;

''(B) propose a design that includes offices for personnel, visiting researchers, and facilities for research and laboratory materials; and

''(C) provide assurances that—

''(i) the facilities shall be available on a fee-for-service or other basis to companies and academic researchers;

''(ii) such services offered to companies and academic researchers shall include testing and validation studies for all types of countermeasures, including detection technology;

''(iii) such facilities shall utilize the research tools identified by the Secretary in section 319F–3 of this Act or certified under section 301(b)(4) of the Project BioShield II Act of 2005; and

''(iv) that the facilities will be constructed as secure facilities.

''(d) DEFINITIONS.—For the purposes of this section—

''(1) unless otherwise specifically identified, the term 'Director' means the Director of the National Institutes of Health;

''(2) the term 'biosafety level 3 facility' means a facility described in section 627.15 of title 32, Code of Federal Regulations (or any successor regulation); and

''(3) the term 'biosafety level 4 facility' means a facility described in section 627.16 of title 32, Code of Federal Regulation (or any successor regulation).

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.''.

(b) NEEDS ASSESSMENT.—The Secretary of Health and Human Services shall conduct a study of regional and national laboratory capacities with respect to the laboratories described in section 319F–7 of the Public Health Service Act (as added by this title) before implementing such section.

TITLE XV—BIODEFENSE AND INFECTIOUS DISEASE RESEARCH AND SCIENTIFIC AND TECHNICAL PERSONNEL

SEC. 1501. ESTABLISHMENT OF GRANT PROGRAM.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

''SEC. 409J. GRANTS FOR BIODEFENSE AND INFECTIOUS DISEASE RESEARCH.

''(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention (referred in this section

as the 'Director'), in consultation with the Assistant Secretary for Medical Readiness and Response of the Department of Homeland Security, and the Secretary of Defense shall establish a program to award grants and scholarships to eligible entities to ensure that sufficient scientific and technical personnel are available to conduct biodefense and infectious disease research.

''(b) ELIGIBILITY.—To be eligible to receive a grant or scholarship under subsection (a), an entity shall—

''(1) be—

''(A) an individual who desires to acquire a scientific or technical skill identified and listed by the Director under subsection (c)(1)(A); or

''(B) a facility or institution that is designated as a scientific or technical skills facility under subsection (c)(1)(B); and

''(2) submit to the Director an application, at such time, in such manner, and containing such information as the Director may require.

''(c) IDENTIFICATION OF SCIENTIFIC AND TECHNICAL SKILLS SHORTAGES.—

''(1) ASSESSMENT AND DESIGNATION.—

''(A) IN GENERAL.—Not later than 1 year after the date of enactment of this section, and

annually thereafter, the Director shall, for purposes of this section, assess the science and technical skills that are needed for the development of medical countermeasures to biological, chemical, nuclear, radiological, and other emerging natural and terrorists threats and infectious diseases, including the expertise needed concerning the identification of drugs, detection equipment, diagnostics, and research tools with respect to such countermeasures. Upon completion of such assessment, the Director shall publish a list of the scientific and technical skills so identified and for which there exists a shortage of qualified individuals.

''(B) FACILITIES.—Not later than 1 year after the date of enactment of this section, and annually thereafter, the Director shall designate public or nonprofit private facilities or institutions that the Director determines provides education or training with respect to a scientific or technical skill identified and published on the list under subparagraph (A).

''(2) LIMITATION ON REMOVAL FROM LIST OR DESIGNATION.—The Director shall not remove a skill from the list under paragraph (1)(A) or a des-

ignation with respect to a facility or institution under paragraph (1)(B) unless the Director has afforded interested persons and groups an opportunity to provide data and information in support of the listing or designation involved, and has made a determination on the basis of the data and information submitted by such persons and groups and other data and information available to the Director.

''(3) CRITERIA.—The Director shall establish by regulation criteria for the listing of skills or designation of facilities and institutions under paragraph (1).

''(4) NOTICE.—The Director shall give written notice of the listing of a skill or designation of a facility or institution not later than 60 days from the date of such designation, to—

''(A) the Governor of each State and official of each local city or town in which the facility or institution so designated is in whole or part located; and

''(B) appropriate public or nonprofit private entities which provide education or training in the skills so listed.

''(5) RECOMMENDED DESIGNATION.—Any person may recommend to the Director the listing or a

skill or designation of a facility or other institution under paragraph (1).

''(6) DISSEMINATION OF CRITERIA.—The Director shall disseminate information concerning the criteria described in paragraph (3) to—

''(A) the Governor of each State;

''(B) the representative of any facility selected by any such Governor to receive such information;

''(C) the representative of any facility that requests such information; and

''(D) the representative of any facility determined by the Director to be likely to meet such criteria.

''(d) USE OF FUNDS.—

''(1) SCHOLARSHIPS.—

''(A) IN GENERAL.—Amounts provided to an individual under a scholarship under subsection (a) shall be used to obtain education leading to a degree or postdoctoral training at a nonprofit institution determined appropriate by the Secretary to further the development of medical countermeasures to biological, chemical, nuclear, radiological, and other emerging terrorists threats and infectious diseases, including

the expertise needed concerning the identification and development of drugs, detection equipment, human and animal remains handling and containment equipment and methods, diagnostics, and research tools with respect to such countermeasures.

''(B) AGREEMENT TO SERVE.—To be eligible to receive a scholarship described in subparagraph (A), an individual shall agree to enter into contract with the Director for obligated service as provided for in subparagraph (C).

''(C) OBLIGATED SERVICE.—An individual who has entered into a written contract with the Director under subparagraph (B) shall conduct countermeasures research on a full-time basis in an area determined appropriate by the Director for the period of obligated service provided for in such contract.

''(D) PERIOD OF SERVICE.—The period of obligated service under a contract under subparagraph (B) shall be equal to the greater of—

"(i) 1 year for each school year for which the individual was provided a scholarship under subsection (a); or

"(ii) 2 years.

"(E) BREACH OF CONTRACT.—The provisions of section 338E shall apply to a breach of contract under this paragraph to the same extent that such provisions apply to a breach of a scholarship contract under such section.

"(2) TRANSITION TO WORKFORCE.—The Director is authorized to provide assistance to Federal agencies to incorporate the individuals who receive a grant under this section into the Federal workforce, including non-tenured positions that could transition into permanent positions at the end of the payback period.

"(3) GRANTS.—Amounts awarded under a grant under subsection (a) shall be used for activities that facilitate the conduct of countermeasures research.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary.".

TITLE XVI—NATIONAL INSTITUTES OF HEALTH

Subtitle A—National Center for Healthcare Technology Development

SEC. 1601. PURPOSE.

The purpose of this subtitle is to enhance the licensing of research, and protect the value of intellectual property, funded by the National Institutes of Health to companies to develop healthcare technologies for the benefit of patients.

SEC. 1602. NATIONAL CENTER FOR HEALTHCARE TECHNOLOGY DEVELOPMENT.

(a) IN GENERAL.—Part E of title IV of the Public Health Service Act (42 U.S.C. 287 et seq.) is amended by adding at the end the following:

''SUBPART 7—NATIONAL CENTER FOR HEALTHCARE TECHNOLOGY DEVELOPMENT

''SEC. 485K. NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY DEVELOPMENT.

''(a) DEFINITION.—In this subpart, the term 'healthcare technology development program' means a program designed to—

''(1) maximize the technology development opportunities and the return on the investment of the

Federal Government in research related to the development of human diagnostics, therapeutics, antimicrobials, vaccines, and research tools so that this investment provides clinical benefits to individuals;

''(2) ensure that research supported by the Federal Government is complimentary to, and not duplicative of or competitive with, private sector research;

''(3) speed the development of biomedical research enabling human diagnostics, therapeutics, vaccines, and research tools; and

''(4) reduce the time and cost necessary for the development of human diagnostics, therapeutics, vaccines, and research tools.

''(b) ESTABLISHMENT; PURPOSE.—

''(1) ESTABLISHMENT.—There is established within the National Institutes of Health a National Center for Healthcare Technology Development (referred to in this subpart as the 'Center').

''(2) PURPOSE.—The purpose of the Center is to increase and support healthcare technology development, which includes—

''(A) maximizing the technology development opportunities and the return on the investment of the Federal Government in re-

search related to the development of human diagnostics, therapeutics, vaccines, and research tools so that this investment provides clinical benefits to individuals;

''(B) ensuring that research supported by the Federal Government is complimentary to, and not duplicative of or competitive with, private sector research;

''(C) speeding the development of biomedical research enabling human diagnostics, therapeutics, vaccines, and research tools; and

''(D) reducing the cost and time necessary for the development of human diagnostics, therapeutics, vaccines, and research tools.

''(c) DIRECTOR.—

''(1) IN GENERAL.—The Center shall be headed by a Center Director (referred to in this section as the 'Center Director') appointed by the President by and with the advice and consent of the Senate.

''(2) COMPENSATION.—The Center Director shall be compensated at a rate that is the greater of—

''(A) the average total compensation of the directors of the national research institutes; or

''(B) level IV of the Executive Schedule.

''(3) DUTIES OF THE CENTER DIRECTOR.—The Center Director shall perform functions as described under this subpart and as the Secretary and the Director of NIH determine appropriate.

''(d) ASSOCIATE DIRECTOR.—

''(1) IN GENERAL.—There shall be in the Center an Associate Director for Biological, Chemical, Radiological, and Infectious Disease Countermeasure Development (referred to in this section as the 'Associate Director'), who shall be appointed by the Center Director.

''(2) DUTIES OF THE ASSOCIATE DIRECTOR.—The Associate Director shall—

''(A) serve as a liaison between the Department of Health and Human Services, the National Institutes of Health, the Department of Homeland Security, and the Department of Defense on matters relating to the development of biomedical technologies that enable effective countermeasures to bioterror, chemical, and radiological agents and infectious diseases;

''(B) ensure that the National Institutes of Health supports research that is consistent with, and supportive of, the joint strategy for the development of countermeasures for bio-

terror, chemical, and radiological agents and infectious diseases of the Department of Homeland Security, the Department of Health and Human Services, and the Department of Defense; and

''(C) annually review the effectiveness of the technology transfer policies and practices of the National Institutes of Health with respect to the development of countermeasures for bioterror, chemical, and radiological agents and infectious diseases to ensure that the policies and practices are consistent with the joint countermeasure development strategy of the Department of Homeland Security, the Department of Health and Human Services, and the Department of Defense.

''(e) DUTIES OF THE CENTER.—The Center shall—

''(1) manage the technology transfer, partnership, and healthcare technology development programs at the National Institutes of Health;

''(2) oversee the healthcare technology development programs of the grantees of the National Institutes of Health;

''(3) secure and license intellectual property for research performed at the National Institutes of Health;

''(4) prepare, on an annual basis, the National Healthcare Technology Development Strategy regarding the technology transfer, partnership, and healthcare technology development programs of the National Institutes of Health and the grantees of the National Institutes of Health;

''(5) with regard to the Healthcare Technology Development Opportunities Assessments under section 492A—

''(A) establish criteria for the contents of the assessments;

''(B) assist National Institutes of Health applicants in preparing the assessments;

''(C) assist the Directors of the national research institutes in reviewing the assessments;

''(D) prepare periodic analyses of the contents of the assessments; and

''(E) prepare periodic analyses of the extent to which the opportunities were realized;

''(6) in consultation with the Directors of the national research institutes, the National Advisory

Council under subsection (f) and the Institute Advisory Councils under subsection (g), prepare a research agenda for the National Institutes of Health, and for each national research institute, that describes—

''(A) the technology development opportunities and the research that would be most beneficial to enhancing the return on the investment of the Federal Government in developing human diagnostics, therapeutics, vaccines, and research tools, so that this investment provides clinical benefits to individuals;

''(B) the research supported by the Federal Government that is complimentary to, and not duplicative of or competitive with, private sector research;

''(C) proposed measures designed to speed the development of human diagnostics, therapeutics, vaccines, and research tools; and

''(D) proposed measures designed to reduce the cost and time necessary to develop human diagnostics, therapeutics, vaccines, and research tools;

''(7) publish a technology transfer, partnership, and healthcare technology development manual that

describes the most effective healthcare technology development policies and practices for the National Institutes of Health and its grantees that maximize the technology development opportunities and the return on the investment of the Federal Government in research to the development of healthcare technology;

''(8) collect and analyze comprehensive data regarding the effectiveness of the technology transfer, partnerships, and healthcare technology development programs of the National Institutes of Health and its grantees that maximize the technology development opportunities and the return on the investment of the Federal Government in research to the development of healthcare technology, including data regarding—

''(A) intellectual property;

''(B) licensing and commercialization of inventions sponsored by the National Institutes of Health;

''(C) cooperative research and development agreements; and

''(D) technology development opportunities assessments under section 492A(a);

''(9) develop guidelines that enable the National Institutes of Health to accept and divest economic interests in commercial entities that enter into technology transfer, licensing, and partnership relationships with the National Institutes of Health;

''(10) accept payment for services, use of equipment, materials, or laboratory personnel, and retain or transfer those funds to the appropriate laboratories;

''(11) ensure that Small Business Innovative Research (SBIR) and Small Business Technology Transfer Program (STTR) grants under section 9 of the Small Business Act (15 U.S.C. 638) are awarded to entities that have the greatest capacity to develop healthcare technology that provides clinical benefits to individuals;

''(12) oversee the review of SBIR and STTR grants;

''(13) annually award the 'Birch Bayh and Robert Dole Award for Healthcare Partnerships' to the individual and to the organization that has made the most significant contribution with regard to—

''(A) maximizing the technology development opportunities and the return on the investment of the Federal Government in re-

search related to the development of human diagnostics, therapeutics, vaccines, and research tools so that this investment provides clinical benefits to individuals;

"(B) ensuring that research supported by the Federal Government is complimentary to, and not duplicative of or competitive with, private sector research;

"(C) speeding the development of biomedical research enabling human diagnostics, therapeutics, vaccines, and research tools; and

"(D) reducing the time and cost necessary to develop human diagnostics, therapeutics, vaccines, and research tools;

"(14) annually award the 'Ronald Reagan and Morris Udall Award for Healthcare Technology Development' to the individual scientist supported by the National Institutes of Health that has made the most significant contribution to the development of healthcare technology that provides clinical benefits to individuals;

"(15) provide grants to private organizations with expertise in technology transfer, partnerships, and healthcare technology development programs;

''(16) manage an education program for National Institutes of Health and private sector entity employees and grantees on the role of the National Institutes of Health concerning the development of healthcare technology; and

''(17) manage the advisory councils under subsections (f) and (g).

''(f) NATIONAL ADVISORY COUNCIL.—

''(1) ESTABLISHMENT.—The Secretary shall establish in the Center an advisory council to be known as the National Healthcare Technology Development Advisory Council (referred to in this subsection as the 'National Advisory Council').

''(2) COMPOSITION.—

''(A) IN GENERAL.—The National Advisory Council shall be composed of 13 members to be appointed in accordance with subparagraph (B) and subject to subparagraphs (C), (D), (E), and (F).

''(B) APPOINTMENT; BACKGROUND.—

''(i) APPOINTMENT.—Not later than 180 days after the effective date of the Project BioShield II Act of 2005, the Director of NIH shall appoint the members of the National Advisory Council.

"(ii) BACKGROUND.—Of the members appointed under clause (i)—

"(I) not less than 9 members shall be executive officers of biotechnology, pharmaceutical, diagnostic, and research tool companies that are currently developing or commercializing healthcare technology;

"(II) not less than 3 members shall be executive offices of small business interests; and

"(III) the remaining members may include investors and investment company executives, securities analysts, experts in the economics of biomedical research and development, experts in intellectual property and technology transfer, Food and Drug Administration regulations, licenses, partnerships, and technology transfer officers of grantees of the National Institutes of Health.

"(C) INSTITUTE ADVISORY COUNCILS.—A member of the National Advisory Council shall

not serve as a member of an Institute Advisory Council under subsection (g).

"(D) EX OFFICIO MEMBERS.—

"(i) IN GENERAL.—The Secretary of Commerce, the Director of the National Science Foundation, and the Director of the National Institute of Standards and Technology shall serve as ex officio members of the National Advisory Council.

"(ii) DESIGNEES.—The officers listed in clause (i) may appoint a designee to perform their functions on the National Advisory Council.

"(E) CHAIRPERSON.—The Director of NIH shall appoint a chairperson of the National Advisory Council from among the council members.

"(F) VACANCY.—Any vacancy in the National Advisory Council shall not affect the powers of the Council and shall be filled in the same manner as the original appointment.

"(3) DUTIES OF THE NATIONAL ADVISORY COUNCIL.—The National Advisory Council shall advise the Center Director regarding policies and procedures that will—

"(A) maximize the technology development opportunities and the return on the investment of the Federal Government in research related to the development of human diagnostics, therapeutics, vaccines, and research tools so that this investment provides clinical benefits to individuals;

"(B) ensure that research supported by the Federal Government is complimentary to, and not duplicative of or competitive with, private sector research;

"(C) speed the development of biomedical research into effective human diagnostics, therapeutics, vaccines, and research tools; and

"(D) reduce the cost and time needed for the development of human diagnostics, therapeutics, vaccines, and research tools.

"(4) POWERS.—

"(A) HEARINGS.—The National Advisory Council may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the National Advisory Council considers advisable to carry out this section.

"(B) INFORMATION FROM FEDERAL AGENCIES.—The National Advisory Council may secure directly from any Federal department or agency such information as the National Advisory Council considers necessary to carry out the provisions of this section. Upon request of the National Advisory Council, the head of such department or agency shall furnish such information to the National Advisory Council.

"(C) POSTAL SERVICES.—The National Advisory Council may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

"(5) PERSONNEL.—

"(A) TRAVEL EXPENSES.—The members of the National Advisory Council shall not receive compensation for the performance of services for the National Advisory Council, but shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the

National Advisory Council. Notwithstanding section 1342 of title 31, United States Code, the Secretary may accept the voluntary and uncompensated services of members of the National Advisory Council.

''(B) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the National Advisory Council without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

''(g) INSTITUTE ADVISORY COUNCILS.—

''(1) ESTABLISHMENT.—The Secretary shall establish in the Center the National Center for Healthcare Technology Development Institute Advisory Councils (referred to in this subsection as the 'Institute Advisory Councils').

''(2) COMPOSITION.—

''(A) IN GENERAL.—Each Institute Advisory Council shall be composed of 13 members appointed in accordance with subparagraph (B) and subject to subparagraphs (C), (D), (E), and (F).

''(B) APPOINTMENT; BACKGROUND.—

''(i) APPOINTMENT.—Not later than 180 days after the effective date of the Project BioShield II Act of 2005, the appropriate Institute Director shall appoint the members of the respective Institute Advisory Council.

''(ii) BACKGROUND.—Of the members appointed under clause (i)—

''(I) at least 9 members shall be executive officers of biotechnology, pharmaceutical, diagnostic, and research tool companies that are currently developing or commercializing healthcare technology; and

''(II) the remaining members shall include investors and investment company executives, securities analysts, experts in the economics of biomedical research and development, experts in intellectual property and technology transfer, Food and Drug Administration regulations, licenses, partnerships, and technology transfer officers of grantees of the National Institutes of Health.

"(C) NATIONAL ADVISORY COUNCIL.—A member of an Institute Advisory Council shall not serve as a member of the National Advisory Council under subsection (f).

"(D) EX OFFICIO MEMBER.—The Center Director, or his or her designee, shall serve as an ex officio member of the Institute Advisory Councils.

"(E) CHAIRPERSON.—The appropriate Institute Director shall appoint a chairperson of the respective Institute Advisory Council from among the council members.

"(F) VACANCIES.—Any vacancy in an Institute Advisory Council shall not affect the powers of the Council and shall be filled in the same manner as the original appointment.

"(3) DUTIES OF THE INSTITUTE ADVISORY COUNCIL.—The Institute Advisory Councils shall advise the Center Director regarding policies and procedures that will—

"(A) maximize the technology development opportunities and the return on the investment of the Federal Government in research related to the development of human diagnostics, therapeutics, vaccines, and research tools so that this

investment provides clinical benefits to individuals;

''(B) ensure that research supported by the Federal Government is complimentary to, and not duplicative of or competitive with, private sector research;

''(C) speed the development of biomedical research into human diagnostics, therapeutics, vaccines, and research tools; and

''(D) reduce the cost and time needed for the development of human diagnostics, therapeutics, vaccines, and research tools.

''(4) POWERS.—

''(A) HEARINGS.—The Institute Advisory Councils may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Institute Advisory Council considers advisable to carry out this section.

''(B) INFORMATION FROM FEDERAL AGENCIES.—The Institute Advisory Councils may secure directly from any Federal department or agency such information as the Institute Advisory Council considers necessary to carry out the provisions of this section. Upon request of

an Institute Advisory Council, the head of such department or agency shall furnish such information to the Institute Advisory Council.

''(C) POSTAL SERVICES.—The Institute Advisory Councils may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

''(5) PERSONNEL.—

''(A) TRAVEL EXPENSES.—The members of the Institute Advisory Councils shall not receive compensation for the performance of services for the Institute Advisory Councils, but shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Institute Advisory Councils. Notwithstanding section 1342 of title 31, United States Code, the Secretary may accept the voluntary and uncompensated services of members of the Institute Advisory Council.

''(B) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to an Institute Advisory Council without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

''(h) TRAINEESHIPS; FELLOWSHIPS.—

''(1) IN GENERAL.—The Secretary, acting through the Center Director, may—

''(A) provide research training and instruction in technology transfer and healthcare commercialization transfer, licenses, partnerships, and healthcare technology development; and

''(B) establish research traineeships and fellowships in technology transfer and healthcare commercialization.

''(2) STIPENDS AND ALLOWANCES.—The Secretary may provide individuals receiving instruction, a traineeship, or fellowship under paragraph (1) with such stipends and allowances, including amounts for travel, subsistence, and dependents, as the Secretary determines necessary.

''(3) EMPLOYEE DETAIL.—The Secretary shall establish guidelines for the temporary leave, for a period of not to exceed 3 years, of not more than

220 employees of the National Institutes of Health, to appropriate for-profit organizations that are in the business of developing human therapeutics, vaccines, devices, or diagnostics and research tools.

''(i) GRANTS.—

''(1) IN GENERAL.—The Secretary, acting through the Center Director, shall award grants to eligible nonprofit institutions to provide training, instruction, traineeships, and fellowships under subsection (h).

''(2) USE OF FUNDS.—A nonprofit institution that receives funds under this subsection shall use the amounts provided through the grant to provide training, instruction, traineeships, and fellowships to individuals under subsection (h) with regard to technology transfer and healthcare development.

''(3) ELIGIBILITY.—To be eligible for a grant under this subsection, a nonprofit institution shall submit an application to the Secretary in such form, in such manner, and containing such information as the Secretary may require.

''(j) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated an amount equal to 0.3 percent of the amount obligated by the National Institutes

of Health in fiscal year 2004 for each fiscal year to carry out this section.''.

(b) GOVERNMENT DISCOUNT.—The Secretary of Health and Human Services and the Secretary of Veterans Affairs shall ensure that the price that the Federal Government pays for a drug, biological product, human therapeutic, vaccine, or diagnostic developed using technology licensed by the National Institutes of Health does not include reimbursement for any royalty rate previously paid by the technology partner or its assign.

SEC. 1603. TECHNOLOGY DEVELOPMENT OPPORTUNITIES ASSESSMENTS.

Section 492A(a) of the Public Health Service Act (42 U.S.C. 289a–1(a)) is amended by adding at the end the following:

''(3) TECHNOLOGY DEVELOPMENT OPPORTUNITIES ASSESSMENT.—Each proposal submitted to the National Institutes of Health shall include an assessment, prepared in compliance with the guidelines developed by the National Center for Healthcare Technology Development, of technology development opportunities, including opportunities that may exist for the proposed research to—

''(A) maximize the technology development opportunities and the return on the investment

of the Federal Government in research related to the development of human diagnostics, therapeutics, vaccines, and research tools so that this investment provides clinical benefits to individuals;

''(B) ensure that research supported by the Federal Government is complimentary to, and not duplicative of or competitive with, private sector research;

''(C) speed the development of biomedical research into human diagnostics, therapeutics, vaccines, and research tools; and

''(D) reduce the cost and time necessary for the development of human diagnostics, therapeutics, vaccines, and research tools.''.

SEC. 1604. RESOURCES FOR THE NATIONAL CENTER FOR HEALTHCARE TECHNOLOGY DEVELOPMENT.

Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (13)(B), by striking ''and'';

(2) in paragraph (14), by striking ''title 38, United States Code.'' and inserting ''title 38, United States Code; and''; and

(3) inserting after paragraph (14) the following:

''(15) after consultation with the Director of the National Center for Healthcare Technology Development, shall develop programs designed to—

''(A) maximize the technology development opportunities and the return on the investment of the Federal Government in research related to the development of human diagnostics, therapeutics, vaccines, and research tools so that this investment provides clinical benefits to individuals;

''(B) ensure that research supported by the Federal Government is complimentary to, and not duplicative of or competitive with, private sector research;

''(C) speed the development of biomedical research into human diagnostics, therapeutics, vaccines, and research tools; and

''(D) reduce the time and cost necessary for the development of human diagnostics, therapeutics, vaccines, and research tools.''.

SEC. 1605. BIENNIAL REPORT OF THE DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH TO THE PRESIDENT AND CONGRESS.

Section 403 of the Public Health Service Act (42 U.S.C. 283) is amended—

(1) in paragraph (4), by striking ''area; and'' and inserting ''area;'';

(2) in paragraph (5), by striking ''Nursing Research.'' and inserting ''Nursing Research; and''; and

(3) by inserting after (5) the following:

''(6) a description of the healthcare technology that has been developed for the clinical benefit of individuals with support by the National Institutes of Health in the preceding 2-year period and the specific contribution of research supported by the National Institutes of Health to this technology.''.

SEC. 1606. AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES; BIENNIAL REPORT.

(a) AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES.—Section 405(b)(1)(A) of the Public Health Service Act (42 U.S.C. 284(b)(1)(A)) is amended—

(1) in clause (iii), by striking ''disabilities, and'' and inserting ''disabilities,'';

(2) in clause (iv), by striking ''the environment;'' and inserting ''the environment, and''; and

(3) by inserting after clause (iv) the following:

''(v) the expansion of knowledge of the creation, manufacture, or administration of treatments of patients suffering from diseases, disorders, or disabilities; and''.

(b) BIENNIAL REPORT.—Section 407 of the Public Health Service Act (42 U.S.C. 284b) is amended to read as follows:

''SEC. 407. INSTITUTE BIENNIAL REPORT.

''(a) IN GENERAL.—The Director of each national research institute, after consultation with the advisory council for the institute, shall include in the biennial report made under section 403—

''(1) a description of the research areas identified as most relevant to the development of technology by the National Center for Healthcare Technology Development Advisory Council;

''(2) a description of the activities of the institute;

''(3) a description of technology that has been developed and licensed for the clinical benefit of individuals from all research supported by the institute; and

''(4) a description of program policies of the Director of the institute.

''(b) ADDITIONAL REPORTS.—The Director of each national research institute may prepare such additional reports as the Director determines appropriate.

''(c) OPPORTUNITY FOR WRITTEN COMMENTS.—The Director of each national research institute shall provide the advisory council for the institute an opportunity for the submission of the written comments described under section 406(g).''.

SEC. 1607. COMMERCIAL RESEARCH AND INVESTIGATIONS.

Section 301(a) of the Public Health Service Act (42 U.S.C. 241(a)) is amended in the matter following paragraph (8) by striking ''for biomedical and behavioral research, substances and living organisms'' and inserting ''for commercial, biomedical, and behavioral research, substances, resources, rights to intellectual property, and living organisms''.

SEC. 1608. SBIR/STTR PROGRAM CONSULTATION WITH THE DIRECTOR OF THE CENTER OF HEALTHCARE TECHNOLOGY DEVELOPMENT.

Section 9 of the Small Business Act (15 U.S.C. 638) is amended—

(1) in subsection (g)(3)—

(A) in subparagraph (A), by striking ''; or'' and inserting a semicolon;

(B) in subparagraph (B), by inserting ''or'' after the semicolon; and

(C) by adding after subparagraph (B) the following:

''(C) the Director of the National Center for Healthcare Technology Development under section 485K of the Public Health Service Act;''; and

(2) in subsection (o)(3)—

(A) in subparagraph (A), by striking ''; or'' and inserting a semicolon;

(B) in subparagraph (B), by inserting ''or'' after the semicolon; and

(C) by inserting after subparagraph (B) the following:

''(C) by the Director of the National Center for Healthcare Technology Development under section 485K of the Public Health Service Act;''.

SEC. 1609. PURPOSE OF THE NATIONAL RESEARCH INSTITUTES.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 410 (42 U.S.C. 285), by inserting before the period the following: '', and the conduct

and support of the development of healthcare technologies'';

(2) in section 418 (42 U.S.C. 285b), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(3) in section 426 (42 U.S.C. 285c), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(4) in section 435 (42 U.S.C. 285d), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(5) in section 443 (42 U.S.C. 285e), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(6) in section 446 (42 U.S.C. 285f), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(7) in section 448 (42 U.S.C. 285g), by inserting before the period the following: '', and the con-

duct and support of the development of healthcare technologies'';

(8) in section 453 (42 U.S.C. 285h), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(9) in section 455 (42 U.S.C. 285i), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(10) in section 457 (42 U.S.C. 285j), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(11) in section 461 (42 U.S.C. 285k), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(12) in section 463 (42 U.S.C. 285l), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(13) in section 464 (42 U.S.C. 285m), by inserting before the period the following: '', and the

conduct and support of the development of healthcare technologies'';

(14) in section 464H (42 U.S.C. 284n), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(15) in section 464L (42 U.S.C. 285o), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(16) in section 464R (42 U.S.C. 285p), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies'';

(17) in section 464V (42 U.S.C. 285q), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies''; and

(18) in section 464Z (42 U.S.C. 285r), by inserting before the period the following: '', and the conduct and support of the development of healthcare technologies''.

SEC. 1610. CONFORMING AMENDMENT.

Section 401(b)(1) of the Public Health Service Act (42 U.S.C. 281(b)(1)) is amended by adding at the end the following:

''(S) The National Center for Healthcare Technology Development.''.

SEC. 1611. EFFECTIVE DATE.

This title shall take effect on October 1, 2005, or upon the date of enactment of this title, whichever occurs later.

Subtitle B—Protecting Government Investment in Basic Biomedical Research

SEC. 1621. FINDINGS.

Congress finds that—

(1) the rate of return on the Federal Government's investment in basic biomedical research is maximized when the intellectual property for that research is effectively transferred to commercial entities for development into healthcare products for the benefit of patients;

(2) intellectual property for research supported by the National Institutes of Health is often not competitive with intellectual property for research supported by private investors due to inefficiencies of the technology transfer process and the con-

sequent erosion of the term of the patents for the technology; and

(3) to protect the Federal Government's investment in basic biomedical research and to maximize the likelihood that technology will be developed into healthcare products, a patent that is not affected by the inefficiencies in the technology transfer process should be granted.

SEC. 1622. UTILIZATION AND AVAILABILITY.

(a) IN GENERAL.—An entity with respect to which an affirmative determination is made under section 301(b)(4) shall maximize the utilization of a research tool involved for the development of countermeasures, including making the research tool available on commercially reasonable terms to other entities certified under section 301(b)(4) to develop countermeasures.

(b) RULE OF CONSTRUCTION.—Nothing in this title or chapter 18 of title 35, United States Code, shall be construed to restrict the right of an entity described in subsection (a) to—

(1) secure and enforce a patent regarding a research tool;

(2) enter into exclusive, revocable, and nontransferable licenses of a research tool; or

(3) impose limits on royalty- or product- reach-through or downstream rights or agreements on future countermeasures, or option rights with respect to a research tool.

SEC. 1623. RESTORATION OF TERM OF UNEXPLOITED PATENTS ON GOVERNMENT SPONSORED INVENTIONS RELATING TO COUNTERMEASURES.

(a) IN GENERAL.—Chapter 14 of title 35, United States Code, is amended by adding at the end the following:

"§ 159. Patent term restoration for unexploited patents on Government sponsored inventions

''(a) DEFINITIONS.—In this section:

''(1) ELIGIBLE GOVERNMENT-SPONSORED INVENTION.—The term 'eligible Government-supported invention' means an invention supported in part by funds appropriated to the National Institutes of Health that may be used to produce a countermeasure to a terror agent, infectious disease or other disease or condition or is subject to the provisions of chapter 18 of title 35, United States Code.

''(2) ELIGIBLE GOVERNMENT PATENT.—The term 'eligible Government patent' means a patent that—

"(A) claims an eligible Government-supported invention;

"(B) has not been extended or restored under section 156, 156a, or 158; and

"(C) has not been licensed prior to a date that is 2 years before the date the patent will expire.

"(3) EFFECTIVE EXPLOITATION OF DATE OF THE PATENT.—The term 'effective exploitation date of the patent' means the date that is the later of—

"(A) the date that the patent is licensed to an entity that is not a Federal agency, as that term is defined in section 201(a), for purposes of development or commercialization of the patented invention; or

"(B) if the patent claims a product, a method of using a product or a method of using a product as defined in section 156(a), the date that such product is approved under section 505(b)(1) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 355(b)(1)) or under section 351 of the Public Health Service Act (42 U.S.C. 262).

"(b) PATENT TERM RESTORATION FOR ELIGIBLE GOVERNMENT PATENTS.—

''(1) IN GENERAL.—Notwithstanding the provisions of section 154, the term of an eligible Government patent shall be restored by a period equal to the number of days starting on the date that the patent is issued and ending on the date of effective exploitation date of the patent.

''(2) LIMITATION.—No eligible Government patent shall be restored under this section unless—

''(A) the Director of the National Institutes of Health (referred to in this section as the 'Director of NIH') determines that the licensing of such patent will assist in the development of countermeasures, medicines, vaccines, and other technology potentially beneficial to patients; and

''(B) prior to the expiration of the patent, the Director of NIH submits an application to the Director to restore the term of the patent under subsection (c).

''(c) PROCEDURE FOR RESTORING TERM OF ELIGIBLE GOVERNMENT PATENT.—

''(1) IN GENERAL.—The Director of NIH shall request restoration of an eligible Government patent by submitting a written application to the Director.

''(2) CONTENTS OF APPLICATION.—An application under this section shall—

''(A) be sent to the Director prior to the date that is 45 days before the patent expires;

''(B) set forth the period of the restoration requested; and

''(C) provide an explanation of the basis of the conclusion of the Director of NIH that the requirements of subparagraph (A) are met with respect to the patent being restored.

''(3) EFFECT OF SECTION.—The Director of NIH shall promulgate regulations to give effect to this section, including procedures that permit the restoration of patents in respect of which title has been transferred under section 202.

''(d) DEFERRAL OF PAYMENT OF PATENT ISSUE FEES FOR ELIGIBLE GOVERNMENT PATENTS.—The Federal agency that has rights in an invention subject to a patent application under chapter 18 may defer the payment of fees under section 41 due for issuance of an eligible Government patent until the date that is 90 days after the date that the patent been licensed to an entity that is not a Federal agency as that term is defined in section 201(a). Not later than 30 days after the date a notice of allowance of the patent application is mailed by the Di-

rector, the applicant shall inform the Director that it is invoking this section with respect to the application. The Director shall issue the patent for the National Institutes of Health-supported technology notwithstanding the nonpayment of the issue fee, subject to the provisions of this section.

''(e) PROCEDURES APPLICABLE TO PATENT TERM RESTORATION APPLICATIONS.—The Director has the authority to accept an application submitted under this section and sections 156, 156a, and 158 after the date specified in such sections in exceptional circumstances or where good cause is shown for the delay in submitting the application, except no application may be accepted under any of these sections more than 30 days after the date specified in such section.

''(f) RULES OF CONSTRUCTION REGARDING RESEARCH TOOLS.—Nothing in this section or chapter 18 of title 35, United States Code, shall be construed to restrict the right of an entity to—

''(i) secure and enforce patents with regard to research tools;

''(ii) enter into exclusive, revocable, and nontransferable licenses of such research tools; or

"(iii) impose limits on royalty- or product-reach-through or downstream rights or agreements on future countermeasures or products, or option rights with respect to a research tool.".

(d) DISCRETIONARY WAIVER OF MARCH-IN RIGHTS AND EXCLUSIVE LICENSING.—

(1) IN GENERAL.—The owner of a patent over which the Government has rights under chapter 18 of title 35, United States Code, may request that a Federal agency under whose funding a subject invention was made may waive rights the Government has under sections 200, 203, and 209 of title 35, United States Code.

(2) REQUESTS.—If a request under paragraph (1) is made within 90 days after the date that the entity obtained title to the patent, the Federal agency shall grant the request.

(e) FEDERALLY OWNED INVENTIONS.—Section 209 of title 35, United States Code, (as amended by section 301) is amended—

(A) by redesignating subsections (f) and (g) as subsections (g) and (h), respectively; and

(B) by inserting after subsection (e) the following:

''(f) TERMS AND CONDITIONS OF EXCLUSIVE LICENSE.—Each exclusive license granted shall include a provision that, at the discretion of the licensee, the licensee may act as the agent for the licensor with respect to any patent for the licensed invention for purposes of extending a patent under section 156a or 158.''.

(d) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 14 of title 35, United States Code, is amended by adding after the item relating to section 158 the following:

''159. Patent term restoration for unexploited patents on Government sponsored inventions.''.

SEC. 1624. ENCOURAGING THE PATENTING OF RESEARCH TOOLS.

Section 200 of title 35, United States Code, is amended by striking ''enterprise without unduly encumbering future research and discovery'' and inserting ''enterprise''.

SEC. 1625. EFFECTIVE DATE.

This title takes effect on October 1, 2005, or upon the date of enactment of this title, whichever occurs later.

Subtitle C—Partnership Challenge Grants

SEC. 1631. PARTNERSHIP CHALLENGE GRANTS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) (as amended by sections 202,

1901, 2101, 2102, and 1401) is amended by inserting after section 319F–7 (as added by section 1401) the following:

"SEC. 319F–8. NATIONAL INSTITUTES OF HEALTH COUNTERMEASURES PARTNERSHIP CHALLENGE GRANTS.

''(a) GRANTS AUTHORIZED.—The Director of the National Institutes of Health (in this section referred to as the 'Director'), in consultation with the Director of the Centers for Disease Control and Prevention, is authorized to award, in consultation with the Foundation for the National Institutes of Health, partnership challenge grants to promote joint ventures between the National Institutes of Health, the Foundation for the National Institutes of Health, its grantees, qualified clinical countermeasures delivery centers, and for-profit biotechnology, pharmaceutical, and medical device industries for the development of countermeasures and research tools.

''(b) REGULATIONS.—The Director shall issue regulations within 90 days of the date of enactment of this section to implement the awarding of grants under subsection (a).

''(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preclude an entity that receives a partnership challenge grant under this section from also

being certified as being eligible for the tax, procurement, intellectual property, and liability incentives provided for under the amendments made by subtitle A of title III of the Project BioShield II Act of 2005.

''(d) SAFETY TRAINING PROGRAM.—The Director of NIH, in consultation with the Director of the Centers for Disease Control and Prevention, shall establish a safety training program for researchers working in biosafety level 3 or 4 facilities.

''(e) TRANSFER OF FUNDS.—The Director is authorized to transfer funds to the Foundation for the National Institutes of Health to be used for partnership grants and other costs associated with administering this section.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each of fiscal years 2004, 2005, 2006, 2007, and 2008 for the purpose of carrying out this section.''

TITLE XVII—DEVELOPMENT OF COUNTERMEASURE RESEARCH AT THE DEPARTMENT OF DEFENSE

SEC. 1701. DEVELOPMENT OF COUNTERMEASURE RESEARCH AT THE DEPARTMENT OF DEFENSE.

There are authorized to be appropriated to the Department of Health and Human Services, including funds

appropriated under the Project BioShield Act of 2004 and this Act, such sums as may be necessary to secure and facilitate the development of countermeasures, as defined in section 319F–3 of the Public Health Service Act (as added by section 202), and infectious disease research at the Department of Defense.

SEC. 1702. REQUEST BY THE DEPARTMENT OF DEFENSE.

(a) IN GENERAL.—Upon request by the Secretary of Defense, the Secretary of Health and Human Services may establish interagency agreements, under terms acceptable to the Secretary of Health and Human Services, in which the Department of Defense may order countermeasures under procurement contracts or procurement pools established by the Secretary of Health and Human Services.

(b) PROCESSING OF ORDERS.—The ordering of a countermeasure under an agreement under subsection (a) (including transfers of appropriated funds between the Department of Defense and the Department of Health and Human Services to pay for such orders) may be conducted pursuant to section 1535 of title 31, United States Code, if such order is processed under the terms established—

(1) by the Secretary in the interagency agreement described under subsection (a) for all other orders; and

(2) in the Project BioShield Act of 2004 and the Project BioShield II Act of 2005 (and the amendments made by such Acts) with respect to the procurement of countermeasures under section 319F–2 and section 319F–1 of the Public Health Service Act.

SEC. 1703. EXPANDED PUBLIC-PRIVATE PARTNERSHIP AGREEMENTS FOR RESEARCH AND DEVELOPMENT.

(a) COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.—

(1) AUTHORITY.—In order to develop countermeasures and research tools, the Secretary of Defense may—

(A) authorize the directors or commanders of laboratories and technical activities to enter into agreements under section 3710a of title 15, United States Code; and

(B) subject to requirements analogous to those governing the licensing of federally owned inventions under section 209 of title 35, United States Code, grant nonexclusive, exclusive, or

partially exclusive licenses, royalty-free or for royalties or other consideration, for computer software developed at a laboratory or technical activity that would, if the information involved were obtained from a non-Federal source, constitute a trade secret or commercial or financial information that is privileged or confidential under the meaning of section 552(b)(4) of title 5, United States Code.

(2) PROTECTION OF SOFTWARE.—The Secretary of Defense shall provide appropriate precautions against the unlicensed dissemination of any software licensed under paragraph (1)(B), including exemption from subchapter II of chapter 5 of title 5, United States Code (commonly known as the Administrative Procedure Act), for a period of up to 5 years after the development of the software by the laboratory or technical activity.

(b) ROYALTIES.—

(1) IN GENERAL.—Except as provided in paragraph (2), any royalties or other payments received by the Department of Defense from licensing computer software under subsection (a)(1)(B) shall be disposed of as follows:

(A) The Department may provide appropriate incentives, from royalties or other payments, to laboratory and technical activity employees who are not developers of such computer software but who substantially increased the technical value of the software.

(B) The Department shall retain the royalties and other payments received until the Department or the laboratory or technical activity involved makes payments to employees of a laboratory or technical activity under subparagraph (A).

(C) The balance of the royalties or other payments shall be transferred by the Department of Defense to the accounts of any of its laboratories and technical activities, with the majority share of the royalties or other payments from any invention going to the account of the laboratory or technical activity responsible for the invention. The royalties or other payments so transferred may be used or obligated by a laboratory or technical activity during the fiscal year in which they are received or during the 2 succeeding fiscal years—

(i) to reward scientific, engineering, and technical employees of the laboratory or technical activity, including developers of sensitive or classified technology, regardless of whether the technology has commercial applications;

(ii) to further scientific exchange among the laboratories and technical activities of the Department;

(iii) for education and training of employees consistent with the research and development missions and objectives of the Department or the laboratory or technical activity, and for other activities that increase the potential for transfer of the technology of the laboratories and technical activities;

(iv) for payment of expenses incidental to the administration and licensing of computer software or other intellectual property made at that laboratory or technical activity, including the fees or other costs for the services of other agencies, persons, or organizations for intellectual

property management and licensing services; or

(v) for scientific research and development consistent with the research and development missions and objectives of the laboratory or technical activity.

(D) All royalties or other payments retained by the Department or laboratory or technical activity after payments have been made pursuant to subparagraphs (A), (B), and (C) that are unobligated and unexpended at the end of the second fiscal year succeeding the fiscal year in which the royalties and other payments were received shall be paid into the Treasury of the United States.

(2) EXCESS PAYMENTS.—If, after payments to employee-developers under paragraph (1), the royalties or other payments received by the Department of Defense in any fiscal year exceed 5 percent of the budget of the Department for that year, 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent may be used or obligated as described in paragraph (1)(C). Any funds not so used or obligated shall be paid into the Treasury of the United States.

(3) TREATMENT OF PAYMENTS.—Any payment made to an employee under this subsection shall be in addition to the regular pay of the employee and to any other awards made to the employee, and shall not affect the entitlement of the employee to any regular pay, annuity, or award to which such employee is otherwise entitled or for which such employee is otherwise eligible or limit the amount thereof. Any such payment made to an employee-developer shall continue after the developer leaves the laboratory or technical activity or the Department. Payments made under this section shall not exceed $150,000 per year to any one person, unless the President approves a larger award (with the amount in excess of $150,000 being treated as a Presidential award under section 4504 of title 5, United States Code).

(c) REGULATIONS.—The Secretary of Defense shall promulgate regulations implementing this section.

(d) INFORMATION IN REPORT.—The report required under section 2515(d) of title 10, United States Code, shall include information regarding the implementation and effectiveness of this section.

(e) LABORATORY AND TECHNICAL ACTIVITY DEFINED.—As used in this section, the terms ''laboratory''

and ''technical activity'' mean any facility or group of facilities that is owned, leased, operated, or otherwise used by the Department of Defense to perform research, development, engineering, testing, or evaluation. The term includes Department of Defense universities, depots, logistics centers, test centers, shipyards, arsenals, or similar organizations that perform these activities in any capacity consistent with their missions, regardless of whether such activities are a primary or substantial element of such missions. This definition also shall be used by Department of Defense entities when entering into cooperative research and development agreements under section 3710a of title 15, United States Code.

(f) EFFECTIVE DATE AND EXPIRATION.—The authority provided for in this section is for a pilot program to test the effectiveness of this authority and shall expire on December 31, 2009.

TITLE XVIII—MILLENNIUM MEDICINE DISCOVERY AWARD

SEC. 1801. MILLENNIUM MEDICINE DISCOVERY AWARD.

Part P of title III of the Public Health Service Act (42 U.S.C. 280 et seq.) is amended by adding at the end the following:

"SEC. 3990. MILLENNIUM MEDICINE DISCOVERY AWARD.

"(a) ESTABLISHMENT OF AWARD.—There is established an award to be known as the Millennium Medicine Discovery Award (referred to in the section as the 'Award').

"(b) PURPOSE OF AWARD.—The Secretary shall present the Award to an individual, institution of higher learning (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or commercial entity that—

"(1) discovers a vaccine or therapeutic that cures or prevents AIDS;

"(2) discovers a vaccine or therapeutics that prevents infection from malaria;

"(3) discovers a new class of anti-microbials; or

"(4) attains another achievement in infectious disease research as determined by the Secretary.

"(c) REGULATIONS.—

"(1) IN GENERAL.—The Secretary shall by regulation establish the medical discoveries for which the Award may be conferred, the amount of the award, and the application process for the Award.

"(2) LIMITATION.—The amount of an Award under this section, which shall be in the form of cash, shall not exceed $100,000,000 per discovery.

''(d) EXAMPLES OF DISCOVERIES.—Discoveries that may qualify for an Award under this section may include 1 of the following:

''(1) An oral vaccine delivery system, or needle-free system, that provides primary immunization against bioterrorism agents, infectious disease, or significant diseases of the developing world.

''(2) A new adjuvant for vectored or recombinant DNA vaccines that induce and sustain both cellular and humeral responses in humans that is directed at bioterrorism agents, infectious diseases, or significant diseases of the developing world.

''(3) A vaccine that provides lifelong protection against HIV–1 infection, or a vaccine that lessens the viral load in those immunized people who become infected or that delays the clinical progression of disease and decreases transmission of the virus through the immunized population.

''(4) A microbicide that prevents or significantly reduces HIV transmission and other infections. In this paragraph, the term 'microbicide' means a range of products, including those products in gel, cream, film, ring, or suppository form that, when applied topically, prevent HIV transmission and other sexually transmitted diseases.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section. The Secretary shall secure ½ of the funding for the Awards under this section from other entities, including nonprofit institutions.''.

TITLE XIX—FOOD AND DRUG ADMINISTRATION

SEC. 1901. OTHER INCENTIVES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319F–3 (as added by section 202) the following:

''SEC. 319F–4. ACCELERATED APPROVAL OF COUNTERMEASURES.

''(a) IN GENERAL.—The Secretary may designate a countermeasure as a fast-track product pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) or as a device granted priority review pursuant to section 515(d)(5) of such Act (21 U.S.C. 366e(d)(5)). Such a designation may be made prior to the submission of—

''(1) a request for designation by the sponsor or applicant; or

''(2) an application for the investigation of the drug under section 505(i) (21 U.S.C. 355(i)) of such Act or section 351(a)(3).

Nothing in this subsection shall be construed to prohibit a sponsor or applicant from declining such a designation.

''(b) USE OF ANIMAL TRIALS.—A drug for which approval is sought under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) or section 351 on the basis of evidence of effectiveness that is derived from animal studies may be designated as a fast-track product for purposes of this section.

''(c) PRIORITY REVIEW.—

''(1) IN GENERAL.—A countermeasure that is a drug or biological product shall be subject to the performance goals established by the Commissioner of Food and Drugs for priority drugs or biological products.

''(2) DEFINITION.—In this subsection, the term 'priority drugs or biological products' means a drug or biological product that is the subject of a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997.''.

SEC. 1902. SYSTEMS BIOLOGY.

(a) FINDINGS.—Congress makes the following findings:

(1) Systems biology, the application of computational tools to understand the dynamic behavior of biological networks as integrated systems rather than isolated parts, is an emerging field of research.

(2) Open-source systems biology can play a role in accelerating understanding of complex biological systems, increasing confidence in the analysis and prioritization of drug targets, enabling predictive toxicology, and other emerging capabilities.

(3) Such capabilities can lead to shorter drug development times, speeding the delivery of needed medication to address public health concerns, and may help decrease or manage the high risks associated with the entire drug development system, resulting in a reduction of the mounting costs of drug development and an increase in the number of new entities brought to market to improve public health.

(b) IMPLEMENTATION OF BIOLOGY RESEARCH PROGRAMS.—The Secretary of Health and Human Services shall promulgate regulations implementing—

(1) systems biology research programs, including systems biology tool development, model development, and integration of such research into experimental frameworks validating and exploiting research results;

(2) research efforts, including systems biology approaches, directed to address the detection of biothreat agents through blood samples; and

(3) such programs described in the Food and Drug Report of March 2004 entitled ''Critical Path Initiative'' that enable the development of tools and methods for the rapid approval of safe medications for the treatment of anticipated biohazards.

SEC. 1903. BIOTERROR AND INFECTIOUS DISEASE PROVISIONS.

(a) BIOTERROR AND INFECTIOUS DISEASE PROVISIONS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter F—Bioterror and Infectious Disease Products

''SEC. 571. DEFINITIONS.

''In this subchapter:

''(1) BIOLOGICAL AGENT.—The term 'biological agent', 'biological toxin', or any variation of any such term, means any microorganism, virus, infectious substance, or biological product, that may be used in a manner that is intended to cause widespread death or serious bodily injury, including biological agents and toxins described in paragraphs (1)

and (2) of section 178 of title 18, United States Code.

''(2) BIOTERROR OR INFECTIOUS DISEASE PRODUCT.—The term 'bioterror or infectious disease product' means a countermeasure against a biological agent.

''(3) COUNTERMEASURE.—The term 'countermeasure' means—

''(A) a vaccine and related delivery system, anti-infective, microbicide, diagnostic technology, drug, biological product, or other technology that can be used to diagnose, treat, or prevent infection with or bodily harm from, or the spread of, a biological or chemical agent or toxin on the list described in section 319F–3(f) of the Public Health Service Act, and that is subject to applicable provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Public Health Service Act (42 U.S.C. 201 et seq.), or the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.);

''(B) a therapy, diagnostic, or piece of equipment that may be used to detect, treat, or prevent bodily harm that may be caused by the

use of nuclear or radiological material as a terror weapon;

"(C) a qualified countermeasure, as defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a); and

"(D) a security countermeasure, as defined in section 319F–2 (42 U.S.C. 246d–6b).

"(4) INFECTIOUS DISEASE.—

"(A) IN GENERAL.—The term 'infectious disease' means a disease in humans caused by—

"(i) a microbe (including a bacteria, virus, fungus, or parasite) that is acquired by a person that reproduces in that person;

"(ii) microbial products (such as botulinum toxin); or

"(iii) a prion.

"(B) INCLUSION.—

"(i) a disease in humans caused by a microorganism, whether or not—

"(I) such microorganism is acquired by an individual through human-to-human contact; or

"(II) if the individual is initially symptomatic of the disease; and

''(ii) zoonotic diseases that may find hosts in animal and human populations.

"SEC. 572. DEPUTY COMMISSIONER FOR BIOLOGICAL, CHEMICAL, NUCLEAR, RADIOLOGICAL, AND INFECTIOUS DISEASE PRODUCTS.

''(a) ESTABLISHMENT OF OFFICE.—There is established within the Office of Counterterrorism of the Office of the Commissioner of the Food and Drug Administration an Office of the Deputy Commissioner for Biological, Chemical, Nuclear, Radiological, and Infectious Disease Products (referred to in this section as the 'Deputy Commissioner').

''(b) DUTIES.—The Deputy Commissioner shall—

''(1) oversee, plan, and direct resources and personnel of the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and other relevant offices within the Food and Drug Administration, toward the evaluation of products for the prevention, surveillance, diagnosis, and treatment of biological, chemical, nuclear, radiological, and emerging infectious disease threats;

''(2) review not less than annually, the progress of such offices with respect to the functions described under paragraph (1); and

''(3) consult with the Commissioner of Food and Drugs with respect to carrying out the duties described under paragraph (1).

''(c) AUTHORITY.—The Deputy Commissioner shall have the authority to address staffing needs and compensation for shortfalls resulting from any waiver of user fees under section 574.

''SEC. 573. ACCELERATED APPROVAL FOR CERTAIN PRODUCTS.

''The Secretary shall, at the request of the sponsor of a new bioterror or infectious disease product, deem such countermeasure a fast track product under section 506 if—

''(1) there is no other countermeasure product approved by the Food and Drug Administration sufficient to respond to the bioterror or pathogen threat addressed by such new product; and

''(2) the bioterror or pathogen threat addressed by such new product is eminent, as determined by the Secretary, in consultation with the Secretary of Homeland Security and the Director of the Centers for Disease Control and Prevention.

''SEC. 574. WAIVER OF USER FEES.

''(a) IN GENERAL.—The Secretary shall waive the assessment of a user fee under chapter VII to the application

and approval of a bioterror or infectious disease product. Such waivers shall not result in a reduction of funds available to the Secretary for conducting review of such applications and approvals.

''(b) LIMITATION.—The Secretary shall not waive an assessment of a user fee under subsection (a) for an applicant more than once.''.

SEC. 1904. APPROVALS OF CERTAIN DRUGS BASED ON ANIMAL TRIALS.

(a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is amended by adding at the end the following: ''In the case of drugs and diagnostic devices for use against infectious disease or lethal or permanently disabling toxic biological, chemical, radiological, nuclear, or other substances, when adequate and well-controlled studies of effectiveness in humans cannot ethically be conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers, and when adequate field trials assessing use of the drug or diagnostic device (in situations such as after accidental or hostile exposure to the substance) have not been feasible or where adequate volumes of human samples for diagnosis from previous exposures is not available, the Secretary may

grant approval based on evidence of effectiveness derived from appropriate studies in animals. The Secretary may promulgate regulations establishing standards, criteria, and procedures for use of the authority contained in the preceding sentence.''.

(b) PUBLIC HEALTH SERVICE ACT.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(k) APPROVAL OF CERTAIN PRODUCTS AND DIAGNOSTIC DEVICES BASED ON ANIMAL TRIALS.—In the case of biological products and diagnostic devices for use against infectious disease, or lethal or permanently disabling toxic biological, chemical, radiological, nuclear, or other substances, when definitive human effectiveness studies in humans cannot ethically be conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers, and when adequate field trials assessing use of the drug (in situations such as after accidental or hostile exposure to the substance) have not been feasible, the Secretary may grant approval based on evidence of effectiveness derived from appropriate studies in animals. The Secretary may promulgate regulations establishing standards, criteria, and procedures for use of the authority provided under this subsection.''.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section (and the amendments made by this section).

SEC. 1905. CLINICAL TRIAL GUIDELINES FOR ANTI-INFECTIVES.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 510 the following:

"SEC. 511. CLINICAL TRIAL GUIDELINES FOR ANTI-INFECTIVES.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of the Project BioShield II Act of 2005, the Secretary, acting through the Commissioner of Food and Drugs, shall issue guidelines for the conduct of clinical trials with respect to anti-microbials, including anti-microbials to treat resistant pathogens, bacterial meningitis, acute bacterial sinusitis, acute bacterial otitis media, and acute exacerbation of chronic bronchitis. Such guidelines shall indicate the appropriate animal models of infection, in vitro techniques, and valid microbiologic surrogate markers.

''(b) REVIEW.—Not later than 5 years after the date of enactment of the Project BioShield II Act of 2005, the Secretary, acting through the Commissioner of Food and

Drugs, shall review and update the guidelines described under subsection (a) to reflect developments in scientific and medical information and technology.''.

SEC. 1906. AUTHORIZATION OF APPROPRIATIONS FOR FDA PURCHASE OF MICROBIOLOGICAL DATA.

(a) IN GENERAL.—There are authorized to be appropriated $3,000,000 for fiscal year 2007 for the purpose of strengthening the ability of the Food and Drug Administration to evaluate antibiotics for the treatment of targeted pathogens.

(b) SOLE PURPOSE.—Such funds shall be used solely for the purpose of contracting with entities that the Secretary of Health and Human Services determines capable of providing national, real-time microbiological data relevant to antibiotic sensitivity of all clinically relevant strains of bacterial pathogens.

SEC. 1907. AUTHORIZATION OF APPROPRIATIONS TO IMPLEMENT PUBLIC HEALTH SERVICE ACTION PLAN TO COMBAT ANTIMICROBIAL RESISTANCE.

To implement the Public Health Service action plan to combat antimicrobial resistance (Public Health Action Plan to Combat Antimicrobial Resistance, Part 1: Domestic Issues (January 18, 2001)) as developed by the Interagency Antimicrobial Resistance Task Force authorized

under section 319E of the Public Health Service Act (42 U.S.C. 247d–5), there are authorized to be appropriated $25,000,000 for fiscal year 2007.

TITLE XX—ANIMAL MODELS

SEC. 2001. ANIMAL MODELS FOR CERTAIN DISEASES.

(a) FINDING.—Congress finds that the development of well-characterized animal models for identified threat agents is crucial for testing the efficacy of medical countermeasures, and that data is crucial for licensure of products to protect the Nation, particularly those animals genetically designed and bred to mimic the disease or toxic response of humans to a particular biological insult.

(b) ESTABLISHMENT OF WORKING GROUP; GRANTS TO STUDY ANIMAL RESPONSES.—Subpart 6 of part C of title IV of the Public Health Service Act (42 U.S.C. 285f et seq.) is amended by adding at the end the following:

"SEC. 447C. ESTABLISHMENT OF WORKING GROUP.

"(a) IN GENERAL.—The Director of the Institute, in consultation with the Assistant Secretary for Medical Readiness and Response of the Department of Homeland Security and the Director of the Centers for Disease Control and Prevention, shall establish a working group to carry out the duties described in subsection (b) (referred to in this section as the 'Working Group').

''(b) DUTIES.—The Working Group shall determine the most pressing scientific gaps in understanding that must be addressed to create accurate animal models used to determine disease processes for agents that threaten humans.

''(c) MEMBERSHIP.—The Working Group shall include not less than one Director of a center in the National Private Research Program.

''SEC. 447D. GRANTS TO STUDY ANIMAL RESPONSES.

''(a) IN GENERAL.—The Secretary, in consultation with the Commissioner of Food and Drugs and the Secretary of Homeland Security, shall—

''(1) establish and award grants under this section to eligible entities to study the physiological responses of certain animal species to bioterrorism agents and other infectious agents; and

''(2) coordinate efforts to identify and develop well-characterized animal models, including correlates of protection, when feasible, for categories of infectious diseases, and classes of toxins considered the most likely threats to human populations, as identified as bioterror agents by the Office of Emergency Preparedness and Response of the Centers for Disease Control and Prevention.

''(b) ELIGIBILITY; APPLICATION.—To be eligible to receive a grant under this section, an entity shall—

''(1) provide assurances to the Secretary that the entity has a biosafety level 3 or 4 facility that is approved by the Centers for Disease Control and Prevention or has a contractual relationship with such a facility; and

''(2) with respect to an animal biosafety lab, provide assurances that such lab is in compliance with the Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act (7 U.S.C. 2131 note); and

''(3) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(c) BENEFITS UNDER PROJECT BIOSHIELD.—

''(1) IN GENERAL.—If the Secretary determines that an entity receiving a grant under this section has successfully and thoroughly created an animal model for the purpose of testing and regulating novel countermeasures, such animal model shall be considered a research tool for purposes of receiving the benefits under the amendments made by the Project BioShield II Act of 2005.

''(2) CLARIFICATION.—An animal model may be developed, and subsequently recommended by the Food and Drug Administration, separately from a countermeasure application so that such animal model is regarded as a research tool for the countermeasure and such Administration may require such recommended animal model in clinical trials to fulfill regulatory requirements.

''(d) DEFINITIONS.—

''(1) BIOSAFETY LEVEL 3 FACILITY.—The term 'biosafety level 3 facility' means a facility described in section 627.15 of title 32, Code of Federal Regulations (or any successor regulation).

''(2) BIOSAFETY LEVEL 4 FACILITY.—The term 'biosafety level 4 facility' means a facility described in section 627.16 of title 32, Code of Federal Regulations (or any successor regulation).

''(3) RESEARCH TOOL.—The term 'research tool' includes the full range of tools that scientists may use in the laboratory, including animal disease models, cell lines, cell line cultures for the production of biologics, monoclonal and polyclonal antibodies, reagents, drug delivery technologies, vaccine adjuvants, laboratory animals, large animals including nonhuman primates and large animals used for

drug production, growth factors, combinatorial chemistry and DNA libraries, antigen libraries, clones and cloning tools (such as PCR or Real Time PCR), methods, laboratory equipment and machines, databases, and other technologies that enable the rapid and effective development of countermeasures, including diagnostics, vaccines, and drugs.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for the development of animals models described under subsection (a)(2).''.

SEC. 2002. ANIMAL MODELS FIVE-YEAR INITIATIVE.

(a) FINDINGS.—Congress finds the following:

(1) The United States Government has made an unprecedented commitment to expanding and advancing the biomedical research program at the National Institutes of Health, and the success of the Government's efforts is contingent upon the availability of quality resources that will enable and enhance all research endeavors ranging from the most basic and fundamental to the most highly innovative.

(2) Biomedical research has relied on such quality resource, the National Primate Research Centers Program, for more than 40 years, for re-

search models and expertise with non-human primates.

(3) The National Primate Research Centers Program is comprised of a network of 8 National Primate Research Centers (referred to in this section ''NPRCs'') that provide centralized housing and care for non-human primates, as well as the facilities and support necessary for research conducted with such primates. Scientists from almost every State use the resources of the NPRCs for a vast array of studies.

(4) As a result of expanded investment in biomedical research from 2000 to 2005, the demand for the resources of the NPRCs has increased significantly, but several important impediments have become barriers to successful non-human primate research, including the limited number of such primates available, the lack of infrastructure to breed and house animals for research, and the need for trained staff for handling and sophisticated care.

(5) In order to remedy such problems, the National Institutes of Health needs to support a Federal advancement initiative for the NPRCs that addresses the necessary upgrades and program capacity expansions.

(b) FIVE-YEAR INITIATIVE FOR PRIMATE CENTERS.—

Subpart 1 of Part E of title IV of the Public Health Service Act (42 U.S.C. 287 et seq.) is amended by—

(1) redesignating the section 481C as added by Public Law 106-505 as section 481D; and

(2) by adding at the end the following:

"SEC. 481E. FIVE-YEAR INITIATIVE FOR PRIMATE CENTERS.

''(a) IN GENERAL.—The Secretary shall provide additional sums to the base grants provided to the National Primate Research Centers by the National Center for Research Resources in order to—

''(1) increase domestic breeding capabilities;

''(2) develop bridging programs to effectively utilize additional primate species;

''(3) increase the quality and capacity of primate housing and breeding facilities and the availability of related state-of-the-art diagnostic and clinical support equipment for primates; and

''(4) increase the number of personnel trained in primate care and management at the National Primate Research Centers.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.''.

TITLE XXI—STRENGTHENING OF THE VACCINE INDUSTRY

Subtitle A—Biologics, Adjuvants, and Cell Culture Development

SEC. 2101. BIOLOGICS MANUFACTURING CAPACITY INCENTIVES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) (as amended by sections 202 and 1901) is amended by inserting after section 319F–4 (as added by section 1901) the following:

"SEC. 319F–5. BIOLOGICS MANUFACTURING CAPACITY INCENTIVES.

''(a) SURVEY AND PLAN.—Not later than 90 days after the date of enactment of the Project BioShield II Act of 2005, the Secretary shall—

''(1) conduct a survey of the biologics manufacturing and filling facilities, including those for the production of antibiotics, vaccines, monoclonal and polyclonal antibodies, recombinant proteins, and plant compounds using cell culture methods, recombinant technology or other techniques, as well as those for the production of antibodies and other blood products from human and animal blood, operating in the United States and determine whether additional manufacturing facilities that will be need-

ed (and if so the number of such facilities) to manufacture and stockpile biologically active materials for bioterrorist attacks or infectious disease outbreaks; and

''(2) develop a plan to ensure that sufficient biologics manufacturing and filling facilities are available in the United States, Canada, Mexico, Europe, and Japan, when they are needed, including an analysis of the feasibility of the Federal Government contracting for the construction and maintenance of such facilities or of providing tax and other incentives for the construction and maintenance of such facilities by private sector entities.

''(b) SUBMISSION TO CONGRESS.—The Secretary shall submit the plan developed under subsection (a)(2) to Congress together with recommendations concerning the manner in which to ensure that the needed biologics manufacturing facilities available for the production of countermeasures under this title are constructed and available, including the siting, design and certification costs, costs of training and recruitment of expert staff, and other costs associated with such facilities.

''(c) INCENTIVES FOR THE CONSTRUCTION OF BIOLOGICS MANUFACTURING FACILITIES AVAILABLE FOR THE PRODUCTION OF COUNTERMEASURES.—The Sec-

retary shall issue regulations regarding the selection of an entity that agrees to operate as a biologics manufacturing facility available for the production of countermeasures under this title in accordance with the plan developed under subsection (a)(2) for the investment tax credit provided under the amendments made by title III of the Project BioShield II Act of 2005. Such regulations shall state when such an entity shall be available and the terms for the use for the production of such countermeasures. If an entity is constructed to produce such countermeasures, such entity shall provide notice that such entity is available to produce such countermeasures.''.

SEC. 2102. BIOLOGICS MANUFACTURING EFFICIENCY INCENTIVES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) (as amended by sections 202, 1901, and 2101) is amended by inserting after section 319F–5 (as added by section 2101) the following:

''SEC. 319F–6. BIOLOGICS MANUFACTURING EFFICIENCY INCENTIVES.

''(a) FINDINGS.—Congress finds that—

''(1) the manufacturing of biologics, which are derived from living organisms, is an art as well as a science;

''(2) the efficiency of the biologics manufacturing process determines the output capacity, purity, and manufacturing cost of antibiotics, vaccines, recombinant proteins, plant compounds, antibodies, and blood products;

''(3) technical advances in manufacturing sciences for biologics can increase the capacity of the Federal Government to ensure that antibiotics, vaccines, recombinant proteins, plant compounds, antibodies, and blood products are available as part of a bioterror or infectious disease plan and to reduce the cost of manufacturing and stockpiling these vaccines, recombinant proteins, plant compounds, antibodies, and blood products; and

''(4) the subjects of research relating to the manufacturing of biologics may include the development of—

''(A) additional well-characterized cell lines or host strains for antibiotics, vaccines, recombinant proteins, plant compounds, and monoclonal and polyclonal antibody production;

''(B) new biologic and chemical standards for use in product testing, including testing of potency and purity;

"(C) improved preservatives for vaccines or other biologics to prolong shelf-life;

"(D) adjuvants that enhance the immune response;

"(E) tests to determine contamination with human or animal viruses or prions;

"(F) improved tests of potency and purity during the manufacturing process, not just for the final product;

"(G) improved characterization of biologics at the macro-molecular level;

"(H) processes that enhance the yield and quality of biologics;

"(I) improved methods that enhance disinfection and sterilization of material and facilities;

"(J) new methods to improve output, manufacturing costs, and product quality with a particular emphasis on downstream processing (separation and purification) where particular bottlenecks occur with much lost product, complexity, and very high costs; and

"(K) improved methods for decontamination of production facilities to enable switching from one product to another.

''(b) SURVEY AND PLAN.—Not later than 180 days after the date of enactment of the Project BioShield II Act of 2005, the Secretary shall—

''(1) conduct a survey of existing biologics manufacturing sciences and determine whether technical advances in such sciences might increase the biologics output capacity and purity, and lower the manufacturing cost of antibiotics, vaccines, recombinant proteins, plant compounds, antibodies, and blood products; and

''(2) develop a plan to provide incentives to enhance scientific research to develop new technologies identified under the survey conducted under paragraph (1), including a list of the possible technologies that may be developed and the possible incentives that may lead to their development.

''(c) SUBMISSION TO CONGRESS.—The Secretary shall submit the plan developed under subsection (b)(2) to Congress together with recommendations concerning the provision of funding or incentives for the conduct of scientific research to develop new technologies relating to biologics manufacturing sciences.

''(d) INCENTIVES.—The Secretary shall establish a program under which entities that agree to develop new technologies, or improve existing technologies, in accord-

ance with the plan developed under subsection (b)(2) are eligible for the tax incentives provided for under the amendments made by section 312 of the Project BioShield II Act of 2005.''.

SEC. 2103. DEVELOPMENT OF VACCINE ADJUVANTS.

(a) FINDINGS.—Congress finds the following:

(1) New vaccines are under development and testing for the control of infectious diseases including human immunodeficiency virus infection, anthrax, avian flu, and many others, and additional infectious diseases can be anticipated with advanced rapid, along with advanced rapid production of vaccine technologies.

(2) Most new vaccines are composed of synthetic, recombinant, or highly purified subunit antigens that are safer than those in use as of the date of enactment of this Act, but their purity can result in a weaker protective response from the vaccine recipient.

(3) Vaccines are administered to protect a healthy population, and any complications with vaccines result in swift and severe public and legal responses.

(4) Adjuvants are chemicals that enhance the specific protective immune response of vaccines.

(5) As of 2005, there is one aluminum salt-based adjuvant used in vaccines licensed in the United States.

(6) Standardized methods to evaluate new vaccine adjuvant safety must be implemented for human vaccines that are to be formulated with novel adjuvants.

(7) Vaccine adjuvants should receive highest priority by the Food and Drug Administration and the National Institute of Allergy and Infectious Diseases, as the failure to develop and approve them will result in the inability to deploy effective countermeasures against bioterrorism or naturally occurring infectious diseases, even when vaccine development is achieved.

(b) VACCINE ADJUVANT PRIORITY.—The Secretary of Health and Human Services shall promulgate regulations that establish—

(1) priority handling procedures, which may included expedited review and fee waivers, at the Food and Drug Administration with respect to vaccine adjuvants; and

(2) methods for evaluating the safety of—

(A) adjuvants, separate from the methods used to evaluate the safety and effectiveness of adjuvants with vaccine agents; and

(B) adjuvants used in conjunction with one or more vaccine agent.

(c) INCENTIVES FOR VACCINE ADJUVANT PRODUCERS.—

(1) IN GENERAL.—Persons that produce adjuvants shall be entitled to receive the incentives under title III (and the amendments made by that title).

(2) DEFENSE OF CERTAIN MALPRACTICE AND NEGLIGENCE SUITS.—Section 224 of the Public Health Service Act (42 U.S.C. 233) (as amended by title III of this Act) shall apply to vaccine adjuvants developed for use in bioterrorism countermeasures or to treat or prevent infectious disease in the same manner as such section applies to covered countermeasures (as defined by such section).

(d) REQUESTS FOR PROPOSALS.—The Secretary of Health and Human Services shall develop and publish in the Federal Register a request for proposals with respect to adjuvant development and production.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary carry out this section.

SEC. 2104. CELL CULTURE OR RECOMBINANT VACCINES.

(a) GRANTS.—The Director of the National Institutes of Health, in consultation with the Commissioner of Food and Drugs and the Director of the Centers of Disease Control and Prevention, may award grants to eligible entities for the development of cell-culture and other vaccine production technologies.

(b) ELIGIBILITY.—To be eligible to receive a grant under this section an entity shall—

(1) be a public or private entity determined appropriate by the Director of the National Institutes of Health; and

(2) prepare and submit to the Director an application at such time, in such manner, and containing such information as the Director may require.

(c) USE OF FUNDS.—An entity shall use amounts received under a grant under this section to carry out activities leading to the development of cell-culture and other vaccine production technology, including the retooling of outdated plants and the construction of new manufacturing plants.

(d) ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION.—To further the goal of increasing the production of cell culture and other vaccines, the Food and Drug Administration shall—

(1) develop updated regulations relating to the approval of cell culture and other vaccines; and

(2) as part of such regulations, provide for priority to be given to the inspection and evaluation of cell culture and other vaccine manufacturing plants.

(e) ACTIVITIES OF THE SECRETARY.—To further the goal of increasing the production of cell culture and other vaccines, the Secretary of Health and Human Services shall—

(1) develop a strategic plan for the distribution of biologicals developed at facilities constructed under a grant under this section in the case of an infectious disease outbreak; and

(2) not later than 6 months after the date of enactment of this Act, submit to the appropriate committees of Congress a report on the strategy developed under paragraph (1) and on the status and use of previous vaccine development grants.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.

Subtitle B—Influenza Vaccine

CHAPTER 1—INFLUENZA VACCINE AWARENESS CAMPAIGN

SEC. 2111. AWARENESS CAMPAIGN AND EDUCATION AND OUTREACH EFFORTS.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399O. AWARENESS CAMPAIGN AND EDUCATION AND OUTREACH EFFORTS.

''(a) CAMPAIGN.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention (in this section referred to as the 'Director'), shall conduct a public awareness campaign and education and outreach efforts each year during the time period preceding the influenza season on each of the following:

''(1) The importance of receiving the influenza vaccine.

''(2) Which populations the Director recommends to receive the influenza vaccine to prevent health complications associated with influenza, including health care workers and household contacts.

''(3) Professional medical education of physicians, nurses, pharmacists, and other health care

providers and such providers' associated organizations.

''(4) Information that emphasizes the safety and benefit of recommended vaccines for the public good.

''(b) OUTREACH TO MEDICARE RECIPIENTS.—

''(1) IN GENERAL.—The Administrator of the Centers for Medicare & Medicaid Services shall, at the earliest possible time in the influenza vaccine planning and production process, reach out to providers of medicare services, including managed care providers, nursing homes, hospitals, and physician offices to urge early and full preordering of the influenza vaccine so that production levels can accommodate the needs for the influenza vaccine.

''(2) RATES OF IMMUNIZATION AMONG MEDICARE RECIPIENTS.—The Director shall work with the Administrator of the Centers for Medicare & Medicaid Services to publish the rates of influenza immunization among individuals receiving assistance under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

''(c) STATE AND PUBLIC HEALTH ADULT IMMUNIZATION ACTIVITIES.—The Director shall support the development of State adult immunization programs that place

emphasis on improving influenza vaccine delivery to high-risk populations and the general population, including the exploration of improving access to the influenza vaccine.

''(d) EFFICACY OF VACCINE.—The Director shall work with appropriate agencies in conducting a study to assess the efficacy of the influenza vaccine.

''(e) EXISTING MODES OF COMMUNICATION.—In carrying out the public awareness campaign and education and outreach efforts under subsections (a) and (b), the Director may use existing websites or structures for communication.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2005 through 2009.''.

CHAPTER 2—ENCOURAGING VACCINE PRODUCTION CAPACITY

SEC. 2121. INCENTIVES FOR THE CONSTRUCTION OF VACCINE MANUFACTURING FACILITIES.

(a) VACCINE MANUFACTURING FACILITIES INVESTMENT TAX CREDIT.—

(1) ALLOWANCE OF CREDIT.—Section 46 of the Internal Revenue Code of 1986 (relating to amount of investment credit) is amended by striking ''and'' at the end of paragraph (1), by striking the period at the end of paragraph (2) and inserting '', and'',

and by adding at the end the following new paragraph:

''(3) the vaccine manufacturing facilities investment credit.''.

(2) AMOUNT OF CREDIT.—Subpart E of part IV of subchapter A of chapter 1 of such Code (relating to rules for computing investment credit) is amended by inserting after section 48 the following new section:

''SEC. 48A. VACCINE MANUFACTURING FACILITIES CREDIT.

''(a) IN GENERAL.—For purposes of section 46, the influenza vaccine manufacturing facilities investment credit for any taxable year is an amount equal to 20 percent of the qualified investment for such taxable year.

''(b) QUALIFIED INVESTMENT.—

''(1) IN GENERAL.—For purposes of subsection (a), the qualified investment for any taxable year is the basis of each influenza vaccine manufacturing facilities property placed in service by the taxpayer during such taxable year.

''(2) VACCINE MANUFACTURING FACILITIES PROPERTY.—For purposes of this section, the term 'influenza vaccine manufacturing facilities property' means real and tangible personal property—

"(A)(i) the original use of which commences with the taxpayer, or

"(ii) which is acquired through purchase (as defined by section 179(d)(2)),

"(B) which is depreciable under section 167,

"(C) which is used for the manufacture, distribution, or research and development of vaccines, and

"(D) which is in compliance with any standards and regulations which are promulgated by the Food and Drug Administration, the Occupational Safety and Health Administration, or the Environmental Protection Agency and which are applicable to such property.

"(c) CERTAIN PROGRESS EXPENDITURE RULES MADE APPLICABLE.—Rules similar to rules of subsections (c)(4) and (d) of section 46 (as in effect on the day before the date of the enactment of the Revenue Reconciliation Act of 1990) shall apply for purposes of this subsection.

"(d) TERMINATION.—This subsection shall not apply to any property placed in service after December 31, 2009.".

(b) TECHNICAL AMENDMENTS.—

(1) Clause (iii) of section 49(a)(1)(C) of such Code is amended to read as follows:

"(iii) the basis of any vaccine manufacturing facilities property.".

(2) Subparagraph (E) of section 50(a)(2) of such Code is amended by inserting "or 48A(c)" before the period.

(3) The table of sections for subpart E of part IV of subchapter A of chapter 1 of such Code is amended by inserting after the item relating to section 48 the following:

"Sec. 48A. Vaccine manufacturing facilities credit.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to property placed in service after December 31, 2004, under rules similar to the rules of section 48(m) of the Internal Revenue Code of 1986 (as in effect on the day before the date of enactment of the Revenue Reconciliation Act of 1990).

CHAPTER 3—ENSURING SUFFICIENT FLU VACCINE SUPPLY

SEC. 2131. VACCINE SUPPLY.

Title XXI of the Public Health Service Act (42 U.S.C. 300aa–1 et seq.) is amended by adding at the end the following:

''Subtitle 3—Influenza Vaccine

''VACCINE SUPPLY

''SEC. 2141. (a) REQUESTS FOR MORE DOSES.—

''(1) IN GENERAL.—Not later than March 15 of each year, the Secretary shall enter into contracts with manufacturers to produce such additional doses of the influenza vaccine as determined necessary by the Secretary.

''(2) CONTENT OF CONTRACT.—A contract for additional doses shall provide that the manufacturer will be compensated by the Secretary at an equitable rate negotiated by the Secretary and the manufacturer for any doses that—

''(A) were not sold by the manufacturer through routine market mechanisms at the end of the influenza season for that year; and

''(B) were requested by the Secretary to be produced by such manufacturer.

''(3) WHEN SUCH VACCINE PURCHASES SHOULD TAKE PLACE.—The Secretary may purchase from the manufacturer the doses for which it has contracted at any time after which it is determined by the Secretary, in consultation with the manufacturer, that the doses will likely not be absorbed by the private market.

''(b) CONTINGENCY PLAN.—The Secretary shall encourage States to develop a contingency plan, in coordination with the Department of Health and Human Services, for maximizing influenza immunization for high-risk populations in the event of a delay or shortage of the influenza vaccine.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.''.

CHAPTER 4—PREPARING FOR A PANDEMIC OR EPIDEMIC

SEC. 2141. PREPARATION FOR INFLUENZA PANDEMIC OR EPIDEMIC; ANTI-VIRALS SUPPLY.

Subtitle 3 of title XXI of the Public Health Service Act, as added by section 2131, is amended by adding at the end the following:

''PREPARATION FOR INFLUENZA PANDEMIC OR EPIDEMIC

''SEC. 2142. (a) ESTABLISHMENT OF A PROTOCOL.—The Secretary, acting through the Director of the National Vaccine Program (referred to in this section as the 'Director of the Program'), shall continue progress on the pandemic preparedness plan and, in consultation with the Director of the Centers for Disease Control and Prevention, establish a protocol to attempt to prevent, prepare for, and respond to an influenza pandemic or epidemic.

Such protocol shall be updated as determined appropriate by the Director of the Program.

''(b) CONTENTS OF PROTOCOL.—The protocol established under subsection (a) shall—

''(1) improve upon the current influenza vaccines and production and dissemination methods; and

''(2) address—

''(A) methods to coordinate dissemination of the influenza vaccine to key populations in the event of an influenza pandemic or epidemic;

''(B) expansion of influenza vaccine manufacturing capacity (including making advance arrangements for ensuring the availability of raw materials) to respond to the needs of the United States during an influenza pandemic or epidemic;

''(C) alternative ways to manufacture or produce the influenza vaccine;

''(D) alternative methods to prevent the spread of, and complications associated with, influenza, including anti-viral medications;

''(E) vaccine manufacturing capacity, production, and dissemination to improve pre-

paredness for immediate pandemic threats, which may include avian influenza;

''(F) a tracking method for publicly and privately sold doses of the influenza vaccine to enable the Director of the Program to determine, after consultation with manufacturers of the influenza vaccine, how much supply is in circulation in the case of an influenza pandemic or epidemic; and

''(G) other issues determined by the Director of the Program to be appropriate.

''(c) COORDINATION; PREPARATION; PREVENTION.—In establishing the protocol under subsection (a), the Director of the Program shall—

''(1) coordinate with health care providers, manufacturers, research institutions, health care organizations, and other expert stakeholders;

''(2) continue building international and national surveillance capacity;

''(3) continue to engage in epidemiological studies and research on novel influenza viruses; and

''(4) assist States with preparedness activities for a rapid State and local response to an influenza pandemic, including exploring methods of making

the influenza vaccine more accessible to the general population.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $150,000,000 for each of fiscal years 2005 through 2009.

''SEC. 2143. INFLUENZA ANTI-VIRALS SUPPLY.

''(a) IN GENERAL.—The Secretary shall establish a stockpile of anti-virals to use for rapid response to an influenza outbreak.

''(b) AMOUNT.—The stockpile established under subsection (a) shall be of sufficient quantity to treat not less than 2 percent of the population of the United States.''.

CHAPTER 5—REPORT AND ADMINISTRATION

SEC. 2151. REPORT TO CONGRESS.

Not later than 180 days after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention, in consultation with the Assistant Secretary for Medical Readiness and Response of the Department of Homeland Security and the Director of the National Institute for Allergy and Infectious Disease of the National Institutes of Health, shall submit a report to Congress that describes alternatives to traditional vaccines and anti-viral therapeutics for viral diseases, including negative immunomodulation compounds that partially

suppress a macrophage-dependent innate immune response of an individual to viral pathogens, in order to decrease morbidity and mortality from an excessive immune response.

SEC. 2152. SIMPLIFIED ADMINISTRATION OF VACCINE SUPPLY.

Section 1928(d)(6) of the Social Security Act (42 U.S.C. 1396s(d)(6)) is amended by inserting before the last sentence the following: ''The Secretary may sell such quantities of vaccines from such supply as the Secretary determines appropriate. Proceeds received from such sales shall be available to the Secretary solely for the purposes of this section and shall remain available until expended.

SEC. 2153. MEDICARE COVERAGE OF VACCINES AND PROPHYLAXIS AS COUNTERMEASURES.

(a) FINDINGS.—Congress finds the following:

(1) In the event of a bioterrorism attack or infectious disease outbreak, it is in the public interest to ensure appropriate and timely voluntary utilization of critical vaccines and other prophylaxis against these pathogens.

(2) Such voluntary utilization in such emergency will be increased if the vaccines and other prophylaxis are covered under Medicare Part B.

(3) Such voluntary utilization reduces adverse impacts on the public health infrastructure and assists in containing the pathogen without the need to impose quarantines.

(4) Coverage and reimbursement for most vaccines and other prophylaxis currently is not available under Medicare Part B.

(5) Medicare Part B does cover diagnostic services as well as drugs and biological products that are administered incident to a physician's services that are not usually self-administered by the patient as long as they are ''reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member''.

(6) The public interest would be served best by extending Medicare Part B coverage and reimbursement to vaccines and prophylaxis that would combat a wide variety of chemical and biological agents, toxins, nuclear and radiological materials, and emerging infectious diseases.

(b) AMENDMENT TO THE SOCIAL SECURITY ACT TO EXTEND COVERAGE.—Section 1861(s)(10)(A) of the Social Security Act (42 U.S.C. 1396x(s)(10)(A)) is amended by inserting '', a vaccine or prophylaxis against any of the agents, toxins, or materials on the list developed by the

Secretary under section 319F–3(f) of the Public Health Service Act and its administration'' after ''pneumococcal vaccine and its administration''.

(c) EFFECTIVE DATE.—The amendment made by subsection (b) shall apply to items furnished on or after the date of enactment of this Act.

TITLE XXII—GAAP ACCOUNTING FOR VACCINE REVENUE RECOGNITION

SEC. 2201. GAAP ACCOUNTING FOR VACCINE PROCUREMENT.

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services and the Secretary of Homeland Security, in consultation with appropriate representatives from the Securities and Exchange Commission (as determined by such Secretaries) shall meet to determine—

(1) how contracts entered into under the Project BioShield Act of 2004 and the Project BioShield II Act of 2005 (and the amendments made by such Acts) may be structured so that a person that enters such a contract can recognized revenue under General Acceptable Accounting Principles accounting rules; or

(2) how the Securities and Exchange Commission may interpret its Staff Accounting Bulletin Number 104 of December 17, 2003, to achieve the result described under paragraph (1).

TITLE XXIII—HUMAN CLINICAL TRIALS AND DRUGS FOR RARE DISEASES AND CONDITIONS

SEC. 2301. EXPANDED HUMAN CLINICAL TRIALS QUALIFYING FOR ORPHAN DRUG CREDIT.

(a) EXPANDED HUMAN CLINICAL TRIALS QUALIFYING FOR ORPHAN DRUG CREDIT.—

(1) IN GENERAL.—Subclause (I) of section 45C(b)(2)(A)(ii) of the Internal Revenue Code of 1986 is amended to read as follows:

"(I) after the date that the application is filed for designation under such section 526, and".

(2) CONFORMING AMENDMENTS.—Clause (i) of section 45C(b)(2)(A) of the Internal Revenue Code of 1986 is amended by inserting "which is" before "being" and by inserting before the comma at the end "and which is designated under section 526 of such Act".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to amounts paid or incurred after December 31, 2003.

(b) PUBLICATION OF FILING AND APPROVAL OF REQUESTS FOR DESIGNATION OF DRUGS FOR RARE DISEASES OR CONDITIONS.—Subsection (c) of section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) is amended to read as follows:

''(c) Not less than monthly, the Secretary shall publish in the Federal Register, and otherwise make available to the public, notice of requests for designation of a drug under subsection (a) and approvals of such requests. Such notice shall include—

''(1) the name and address of the manufacturer and the sponsor;

''(2) the date of the request for designation or of the approval of such request;

''(3) the nonproprietary name of the drug and the name of the drug under which an application is filed under section 505(b) of this Act or section 351 of the Public Health Service Act;

''(4) the rare disease or condition for which the designation is requested or approved; and

''(5) the proposed indication for use of the product.''.

TITLE XXIV—HEALTHCARE SYSTEM COLLECTION OF CLINICAL DATA REGARDING SAFETY AND EFFECTIVENESS OF COUNTERMEASURES

SEC. 2401. FINDINGS; DEFINITIONS.

(a) PURPOSE.—The purpose of this title is to provide necessary protocols and funding to ensure that real time clinical data about a countermeasure, as it is utilized, may be extracted in order to assess the appropriate role of such countermeasure in responding to a terror attack or outbreak of infectious disease.

(b) DEFINITIONS.—In this title:

(1) CLINICAL COUNTERMEASURES DELIVERY.—The term ''clinical countermeasures delivery'' refers to the coordinated development, implementation, and evaluation of consistent clinical countermeasures policies, diagnostic procedures and protocols, education and training, and necessary medical capacities (such as administrative support, infrastructure including healthcare epidemiology, laboratories, information systems, leadership and expert personnel, research capability, equipment and supplies) for the healthcare delivery and response community within a defined geographic area that takes into account pop-

ulations at risk and vulnerabilities to pathogens and agents.

(2) CLINICAL COUNTERMEASURES DELIVERY CENTER.—The term ''clinical countermeasures delivery center'' means a nonprofit health or public health, medical center, or public hospital, including an academic health center or other similar organization, that dedicates a significant percentage of its resources for the coordination of healthcare delivery, research, education, and integrated community services, as determined by the Assistant Secretary for Medical Readiness and Response of the Department of Homeland Security.

(3) EMERGENCY SITUATION.—The term ''emergency situation'' means a natural or man-made event that requires an emergency response and is designated as an emergency by the President, a Governor through an appropriate State emergency management coordinator, local government executive, or a county emergency manager (only with respect to a condition for a period not to exceed 24 hours pending review and approval by a Governor) in which clinical countermeasures may or will be utilized.

(4) HEALTHCARE DELIVERY AND RESPONSE COMMUNITY.—The term ''healthcare delivery and response community'' means individuals, entities, and institutions that provide—

(A) direct patient healthcare, public health, or community health; or

(B) emergency medical care, such as emergency medical, fire, and police services.

(5) QUALIFIED CLINICAL COUNTERMEASURES DELIVERY CENTER.—The term ''qualified clinical countermeasures delivery center'' means a clinical countermeasures delivery center that has been certified under section 2402 as in compliance with the requirements of section 2403.

(6) ASSISTANT SECRETARY.—The term ''Assistant Secretary'' means the Assistant Secretary for Medical Readiness and Response of the Department of Homeland Security.

SEC. 2402. CERTIFICATION OF CLINICAL COUNTERMEASURES DELIVERY CENTERS.

(a) ESTABLISHMENT OF PROGRAM.—The Assistant Secretary shall establish and administer a program to certify clinical countermeasures delivery centers as qualified clinical countermeasures delivery centers for purposes of ensuring that—

(1) the coordinated development, implementation, and evaluation of clinical countermeasures will precede and follow the utilization of the clinical countermeasures developed under this Act (or the amendments made by this Act) or otherwise available to respond to a biological, chemical, nuclear, radiological, or explosive event or other emergency situation; and

(2) such countermeasures are delivered to affected and at-risk populations within a therapeutically effective time period.

(b) APPLICATION.—

(1) IN GENERAL.—To be certified as a qualified clinical countermeasures delivery center, a clinical countermeasures delivery center shall submit to the Assistant Secretary an application at such time, in such manner, and containing such information as the Assistant Secretary shall require.

(2) APPROVAL.—In determining whether to approve an application under paragraph (1), the Assistant Secretary shall ensure that the clinical countermeasures delivery center is in compliance with the criteria developed pursuant to section 2403.

(c) REQUIREMENTS.—Upon approval of an application under subsection (b), a qualified clinical counter-

measures delivery center within a specified geographic area and representing an affected or at risk population, shall—

(1) during the pre-event phase, develop, test (through exercises), and have in place plans for clinical countermeasures delivery, in accordance with section 2404;

(2) during the pre-event phase, prepare, test, and have in place plans to develop new, and to maintain existing, collaborations with members of the healthcare delivery and response community;

(3) during the event phase, deliver clinical countermeasures to affected and at-risk populations in a therapeutically effective time period and provide medical management and treatment of adverse events arising from utilization of clinical countermeasures developed in response to an emergency situation;

(4) during the event phase, communicate preliminary findings regarding the delivery and efficacy of clinical countermeasures to appropriate Federal, State, and local public health authorities;

(5) during the post event phase, have in place a validated process of metrics and measures for evaluating the effectiveness of clinical countermeasures

through clinical research, including external evaluation, quality assurance and mitigation, and an evaluation of the clinical countermeasures delivery center's capability to respond to the needs of populations at risk and address potential hazard vulnerabilities; and

(6) during the post-even phase, share information about the effectiveness of countermeasures and the capability of the countermeasure delivery centers to respond to the event to appropriate Federal, State, and local public health authorities.

(d) STANDARDS.—The Assistant Secretary shall set standards to ensure that qualified clinical countermeasures delivery centers remain prepared to fulfill the functions described under this section in the event of an emergency situation.

SEC. 2403. ELIGIBILITY CRITERIA.

(a) IN GENERAL.—The Assistant Secretary shall establish by regulation criteria for the certification of clinical countermeasures delivery centers as qualified clinical countermeasures delivery centers for purposes of this title.

(b) MINIMUM QUALIFICATIONS.—The criteria developed under subsection (a) shall require that a qualified clinical countermeasures delivery center—

(1) be a nonprofit healthcare provider that is directly affiliated with an accredited medical teaching institution, accredited school of public health, or an institution of higher education (as defined by section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a))); and

(2) have in place—

(A) plans for clinical countermeasures delivery in accordance with section 2404;

(B) collaborating agreements with members of its healthcare delivery and response community;

(C) plans to participate annually in at least 1 major exercise of plans and systems demonstrating coordination among representatives of its healthcare delivery and response community, as evaluated by the Secretary;

(D) operating and managing clinical plans to deliver healthcare to affected and at risk populations in response to an emergency situation; and

(E) a validated process—

(i) of metrics and measures for evaluating the effectiveness of the delivery center's capability to meet the needs of af-

fected and at risk populations and address potential vulnerabilities to hazards; and

(ii) for sharing the results and data from the plans and activities required under this subsection.

SEC. 2404. POLICIES, PROCEDURES, AND PROTOCOLS FOR THE DELIVERY OF CLINICAL COUNTERMEASURES.

(a) IN GENERAL.—The Assistant Secretary, in consultation with the Commissioner of the Food and Drug Administration, the Director of the Centers for Disease Control and Prevention, the Health Resources Services Administration, the Commissioner of Medicare and Medicaid, and other regulatory and accreditation agencies, as appropriate, shall establish policies, procedures, and protocols to ensure the coordinated delivery of clinical countermeasures as described in section 2402(c).

(b) DESCRIPTION.—The policies, procedures, and protocols established under subsection (a) shall be designed to—

(1) foster cooperation and coordination among qualified clinical countermeasures delivery centers;

(2) ensure the implementation, delivery and evaluation of clinical countermeasures among the healthcare delivery and response community; and

(3) identify and address the clinical, operational, ethical, and legal issues that may arise during an emergency situation.

(c) DUTIES OF CENTERS.—The qualified clinical countermeasures delivery centers shall—

(1) meet the requirements described in subparagraphs (A) and (B) of section 2403(b)(2);

(2) participate annually in at least 1 major exercise of plans and systems demonstrating the coordination of clinical countermeasures among representatives of its healthcare delivery and response community;

(3) have in place operating and clinical plans—

(A) to deliver clinical countermeasures within a therapeutically effective time period to affected and at risk populations in response to an emergency situation; and

(B) for the medical management and treatment of adverse events arising from utilization of clinical countermeasures developed in response to an emergency situation; and

(4) have in place a validated process—

(A) of metrics and measures for—

(i) evaluating the effectiveness of clinical countermeasures, including external

evaluation, quality assurance, and mitigation; and

(ii) evaluating the clinical countermeasures delivery center's capability to meet the needs of affected and at risk populations and address potential vulnerabilities to hazards; and

(B) for sharing the results and data from the plans and activities required under this subsection.

SEC. 2405. INCENTIVES FOR QUALIFIED CLINICAL COUNTERMEASURES DELIVERY CENTERS.

A clinical countermeasures delivery center that is certified by the Assistant Secretary as a qualified clinical countermeasures delivery center—

(1) shall be entitled to reimbursement—

(A) for the costs associated with preparedness for clinical countermeasures delivery and maintaining readiness for a healthcare emergency requiring the use of clinical countermeasures, including training exercises and educational programs;

(B) for costs associated with the implementation, delivery, and evaluation of clinical countermeasures in the event of a healthcare

emergency in which clinical countermeasures, including those developed under this Act (or the amendments made by this Act), are utilized; and

(C) for costs associated with the post-event initiatives involved with the delivery of clinical countermeasures in the event of a healthcare emergency in which clinical countermeasures, including those developed under this Act (or the amendments made by this Act), are utilized; and

(2) at the discretion of the Assistant Secretary, may receive 1 or more of the following:

(A) Bonus payment under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) for the reimbursement of expenditures incurred in connection with the implementation of activities under this title.

(B) Increased graduate medical education reimbursement for expenditures incurred in connection with the implementation of activities under this title.

(C) The application and receipt of surcharges with respect to reimbursements under

the Medicare or Medicaid programs under title XVIII or XIX of the Social Security Act (42 U.S.C. 1395 or 1396 et seq.) paid to the qualified clinical countermeasures delivery centers.

(D) Participation in a program to receive temporary personnel replacements, salary reimbursements, and training cost reimbursement, to be applied to the personnel of qualified clinical countermeasures delivery centers that choose to obtain specialized training in emergency preparedness or that want to obtain special certifications.

(E) Malpractice and tort liability indemnification for the qualified clinical countermeasures delivery centers and the personnel supporting such centers for legal fees and judgments incurred in connection with the implementation of activities under this title.

(F) Worker's compensation indemnification with respect to qualified clinical countermeasures delivery centers' personnel in connection with the implementation of programs under this title during periods of training and emergency situations.

(G) Notwithstanding the requirements of section 1867 of the Social Security Act (42 U.S.C. 1395dd), commonly known as the Emergency Medical Treatment and Active Labor Act, the ability of qualified clinical countermeasures delivery centers to pre-triage patients during an emergency situation, including triaging based on nonemergent conditions to other hospitals, ambulatory facilities, or other appropriate healthcare entities.

(H) Indemnification by the Federal Government for legal fees incurred by the qualified clinical countermeasures delivery centers during an emergency situations, as well as worker's compensation and overall liability coverage during such a situation and during periods of training.

(I) The assistance of Federal personnel or armed forces personnel for the planning and support of training and training exercises for the personnel of the qualified clinical countermeasures delivery centers.

(J) The provision of family support services for workers, including emergency management and public health agencies personnel, sup-

porting the center during an emergency situation to allow for communication access to such workers during such situation, priority standing for access to vaccines and other recommended interventions, and other services to help workers function effectively in such a situation.

SEC. 2406. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as may be necessary to carry out this title.

TITLE XXV—CENTERS FOR DISEASE CONTROL AND PREVENTION

SEC. 2501. GLOBAL DISEASE DETECTION TRUST FUND.

(a) IN GENERAL.—

(1) ESTABLISHMENT OF FUND.—There is established within the Centers for Disease Control and Prevention a Global Disease Detection Trust Fund (referred to in this title as the ''Detection Trust Fund'').

(2) ADMINISTRATION.—The Detection Trust Fund shall be administered by the Director of the Centers for Disease Control and Prevention.

(3) PURPOSES.—The purposes of the Detection Trust Fund are to—

(A) detect, verify, and respond to infectious disease outbreaks around the world more quickly, including threats such as avian influenza and the development of antimicrobial resistance that emerge outside the United States;

(B) control intentional or naturally occurring health threats at their origin and prevent international spread;

(C) protect the health and safety of United States citizens and officials traveling or living abroad; and

(D) protect the economic interests of the United States and its partners from threats to health.

(b) USE OF FUND.—

(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may expend not more than $250,000,000 in each fiscal year from the Detection Trust Fund on global disease detection activities, which may include—

(A) conducting—

(i) disease surveillance activities;

(ii) field investigations;

(iii) training and development activities; and

(iv) research on methods and approaches for detection and control of threats to health described in subsection (a)(3);

(B) developing information and communications technology;

(C) improving infectious disease epidemiology;

(D) providing technical assistance for disease prevention and control programs;

(E) ensuring the capacity to prepare for and respond to emerging and unknown public health threats and emergencies; and

(F) developing and maintaining of laboratory capacity.

(2) LIMITATION.—Amounts expended from the Detection Trust Fund shall not be funded through reductions in the annual appropriations for related activities of the Centers for Disease Control and Prevention.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $1,250,000,000 to the Detection Trust Fund to carry out this section.

SEC. 2502. ENVIRONMENTAL MICROBIOLOGY FACILITY STUDY AND REPORT.

Not later than 6 months after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall—

(1) conduct a study on the feasibility of developing an environmental microbiology facility as part of the National Interagency Biodefense Campus at Fort Detrick, Maryland; and

(2) submit to Congress a report that describes the findings of the study under paragraph (1), including—

(A) the need for such a facility and the potential benefits of developing such a facility as part of the Interagency campus;

(B) the feasibility of constructing such a facility, and

(C) the projected cost and timetable for the construction of such a facility.

SEC. 2503. ENFORCEMENT OF QUARANTINES.

(a) PENALTIES.—Section 368 (42 U.S.C. 271) is amended—

(1) in subsection (a), by striking ''$1,000 or by imprisonment for not more than one year'' and inserting ''$250,000 or by imprisonment for not more than 10 years''; and

(2) in subsection (b), by striking ''$5,000'' and inserting ''$1,000,000''.

(b) PANEL PHYSICIAN QUALITY CONTROL.—Section 361 of the Public Health Service Act (42 U.S.C. 264) is amended by adding at the end the following:

''(f) Where the United States enters into agreements, contracts, or other arrangements with physicians or other healthcare providers and laboratories in foreign countries for the purpose of conducting health screening on aliens seeking temporary or permanent residence in the United States, the Secretary shall evaluate each such physician or provider on an annual basis to certify that the physician or provider adequately complies with applicable regulations governing the medical screening of applicants for entry into the United States. The Secretary may assess certification or user fees to support the annual evaluation, quality control, and certification of panel physicians performing such foreign medical screenings.''.

SEC. 2504. EDUCATIONAL CAMPAIGN AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall, in consultation with relevant stakeholders, carry out a 2-phase, national educational campaign to make available information about the possible public health measures that might be imple-

mented in the event of a pandemic outbreak or a bioterror attack involving an infectious disease.

(b) CAMPAIGN CONTENT.—

(1) IN GENERAL.—The campaign established under subsection (a) may include information regarding—

(A) the circumstances under which a range of public health measures might be implemented;

(B) the concepts of person-to-person spread, quarantine, isolation, and movement restriction;

(C) mass pre- and post-exposure prophylaxis, the use of off-label drugs, and other extraordinary measures to protect the public health;

(D) the rationale and benefits to the public of implementing such public health measures; and

(E) the legal rights of citizens in the event such public health measures are implemented.

(2) CAMPAIGN PHASE 1.—

(A) IN GENERAL.—In Phase 1 of the campaign established under subsection (a), the Director of the Centers for Disease Control and

Prevention shall consult with a diverse advisory panel in the preparation of nationally standardized messages and guidance about the range of medical and nonmedical interventions to interrupt disease transmission.

(B) COMPOSITION OF ADVISORY PANEL.—The advisory panel consulted under subparagraph (A) shall include—

(i) representatives of State and local governments and nongovernmental public health agencies;

(ii) public health experts and medical practitioners who have real-world experience in crisis management and risk communication;

(iii) business leaders;

(iv) members of the lay public; and

(v) subject matter experts in bioethics, risk communication, health education, community organization, advertising, and public relations.

(C) COLLECTION OF INFORMATION.—To direct the deliberations of the advisory panel, the Director of the Centers for Disease Control and Prevention shall collect and synthesize ex-

tant information regarding community-level disease containment measures, including assessment of interventions during the SARS outbreak.

(3) CAMPAIGN PHASE 2.—

(A) PURPOSE.—The purpose of Phase 2 of the campaign established under subsection (a) shall be to augment at the State and local level nationally standardized messages to address specific community needs and concerns.

(B) ESTABLISHMENT OF GRANT.—

(i) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall award grants to 5 local health departments (that are regionally and demographically diverse) to design and deliver educational campaigns targeted for their community with respect to the plans of the health departments for implementing a range of public health interventions in the context of a pandemic outbreak or biological attack.

(ii) APPLICATION.—Local public health departments shall submit to the Secretary an application to receive a grant

under clause (i) at such time, in such manner, and containing such information as the Secretary may require.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $20,000,000 for each of fiscal years 2006 through 2010 to carry out this section.

TITLE XXVI—ZOONOTIC DISEASE SURVEILLANCE

SEC. 2601. ZOONOTIC DISEASE SURVEILLANCE.

(a) FINDINGS.—Congress makes the following findings:

(1) Seventy percent of the known bioterrorist agents are zoonotic.

(2) Emerging infectious diseases such as SARS, monkeypox, and West Nile virus have emerged from animal origins.

(2) Early warning of impending zoonotic disease outbreaks has failed in sentinel animal populations during zoonotic outbreaks such as SARS, monkeypox, and West Nile virus.

(3) There is no way to predict what species might serve as sentinels in emerging infectious diseases or bioterrorist events.

(4) Many animals, such as dogs, cats, and exotic pets, do not fall under the jurisdiction of any Federal agency.

(5) There is a lack of focus on the detection of zoonotic threats in sentinel or reservoir animal populations prior to human involvement.

(6) There is a continued inability to share real-time data across the human and veterinary agencies on zoonotic threats.

(b) ESTABLISHMENT OF WORKING GROUP.—The Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of the Interior, and the Secretary of Defense shall establish a Zoonotic Disease Working Group within the Department of Homeland Security (referred to in this section as the ''Working Group'').

(c) DUTIES OF WORKING GROUP.—

(1) IN GENERAL.—The Working Group shall conduct a study of all matters relating to the creation of an integrated (human and animal) real-time zoonotic disease surveillance network and make recommendations that address gaps in surveillance activities.

(2) MATTERS STUDIED.—The Working Group shall—

(A) evaluate the status of zoonotic disease surveillance by Federal agencies and the private sector as of the date of enactment of this Act;

(B) identify—

(i) existing bioterrorism funds in Federal and State agencies;

(ii) budgets that could be redirected toward improving the ability to detect and report zoonotic threats across species handled by veterinary and wildlife institutions; and

(iii) existing laboratory facilities for zoo animals, pets, and exotic collections that could be networked, equipped, and funded for such purpose; and

(C) consult private sector representatives, including those with expertise on non-agricultural species, exotic pets, and zoo animals, representatives of State and local public health agencies, and representatives from veterinarians and laboratories.

(3) SUBMISSION OF REPORT.—Not later than 8 months after the date of enactment of this Act, the Working Group shall submit a report to the Sec-

retary of Homeland Security with respect to its findings and recommendations under this section.

TITLE XXVII—COUNTERMEASURES AGAINST AGROTERRORISM

SEC. 2701. FINDINGS.

Congress finds that—

(1) agriculture is important to the social and economic stability of the United States;

(2) in 2001, food production constituted 9.7 percent of the gross domestic product of the United States, generating cash receipts in excess of $991,000,000,000;

(3) the agriculture production and food industries are vulnerable to deliberate agroterrorist acts and naturally occurring disease disruption;

(4) practices that heighten this vulnerability include—

(A) the highly intensive and concentrated nature of agribusiness in the United States, which increases the potential speed with which a disease can spread;

(B) the insufficiency of agricultural security methods and biosurveillance technologies;

(C) the hesitancy of producers to report disease outbreaks for fear of uncompensated culling or quarantine;

(D) the declining pool of veterinarians and diagnosticians trained to recognize foreign animal diseases;

(E) larger breeding herds, which reduce individual animal health observations and may cause illnesses to remain undetected; and

(F) inadequate laboratory diagnostic capability at the national and local levels;

(5)(A) countermeasures should be developed to both prevent and control agroterrorism;

(B) incentives under title III (and amendments made by that title) should be made available to persons who develop and manufacture those countermeasures;

(C) threats to biosecurity should be identified through cooperative decisions made by the Secretary and the Secretary of Homeland Security;

(D) the Secretary regulates and approves biological and chemical agents and toxins under the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.); and

(E) the Secretary of Health and Human Services, acting through the Center for Veterinary Medi-

cine of the Food and Drug Administration, regulates and approves new animal drugs under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b);

(6) preventative countermeasures (including all equipment, materials, drugs, personnel, and training necessary to interdict the spread of animal and plant diseases efficiently and effectively) should include—

(A) increased funding for the Animal and Plant Health Inspection Service to increase training and better protect the borders of the United States;

(B) increased funding for exotic animal and plant disease research conducted in countries in which exotic diseases are endemic;

(C) improved use, by persons under contract with the Federal Government to develop countermeasures, of appropriate containment facilities controlled by the Federal Government (such as the National Veterinary Disease Laboratory in Ames, Iowa or Plum Island, New York); and

(D) increased funding for vaccine and antibiotic research;

(7) control countermeasures should include—

(A) recruiting, training, and equipping field personnel;

(B) developing rapid and specific diagnostic tests;

(C) developing a stockpile of countermeasures to biological and chemical agents and toxins of consequence to the agricultural community, as determined by the Secretary, with adequate funding for the development of the stockpile;

(D) researching and stockpiling of antiviral, antifungal, antibacterial, and vector control agents; and

(E) a national system of livestock identification and movement surveillance; and

(8) an effective system of countermeasures against agroterrorism will require initial centralization followed by dissemination of policies and practices to a local level.

SEC. 2702. DEFINITIONS.

In this Act:

(1) AGRICULTURAL DISEASE.—The term ''agricultural disease'' means an outbreak of a plant or animal disease, or a pest infestation, that requires prompt action in order to prevent injury or damage

to people, plants, livestock, property, the economy, or the environment.

(2) AGRICULTURAL DISEASE EMERGENCY.—The term ''agricultural disease emergency'' means an agricultural disease that the Secretary determines to be an emergency under—

(A) section 415 of the Plant Protection Act (7 U.S.C. 7715); or

(B) section 10407(b) of the Animal Health Protection Act (7 U.S.C. 8306(b)).

(3) AGRICULTURE.—The term ''agriculture'' includes—

(A) the science and practice of activities relating to food, feed, and fiber production, processing, marketing, distribution, use, and trade;

(B) family and consumer science, nutrition, food science and engineering, agricultural economics, and other social sciences; and

(C) forestry, wildlife science, fishery science, aquaculture, floraculture, veterinary medicine, and other environmental and natural resource sciences.

(4) AGROTERRORISM.—The term ''agroterrorism'' means the commission of an agroterrorist act.

(5) AGROTERRORIST ACT.—The term ''agroterrorist act'' means a criminal act consisting of causing or attempting to cause damage or harm to, or destruction or contamination of, a crop, livestock, farm or ranch equipment, material or property associated with agriculture, or a person engaged in agricultural activity, that is committed with the intent—

(A) to intimidate or coerce a civilian population; or

(B) to influence the policy of a government by intimidation or coercion.

(6) BIOSECURITY.—

(A) IN GENERAL.—The term ''biosecurity'' means protection from the risks posed by biological, chemical, or radiological agents to—

(i) plant or animal health;

(ii) the agricultural economy;

(iii) the environment; or

(iv) human health.

(B) INCLUSIONS.—The term ''biosecurity'' includes the exclusion, eradication, and control

of biological agents that cause plant or animal diseases.

(7) COUNTERMEASURE.—The term ''countermeasure'' has the meaning given that term in section 319F–3 of the Public Health Service Act (as added by section 202).

(8) INDIAN TRIBE.—The term ''Indian tribe'' has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Agriculture.

(10) TRIBAL GOVERNMENT.—The term ''tribal government'' means the governing body of an Indian tribe.

SEC. 2703. ESTABLISHMENT OF WORKING GROUP.

The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of Homeland Security, shall establish a working group (referred to in this title as the ''Working Group'') that shall include representatives of—

(1) appropriate agencies of the Department of Agriculture, appointed by the Secretary;

(2) the Centers for Disease Control and Prevention, appointed by the Secretary of Health and Human Services;

(3) the Center for Veterinary Medicine of the Food and Drug Administration, appointed by the Secretary of Health and Human Services, in consultation with the Secretary of Defense and the Secretary of Homeland Security;

(4) the Department of Homeland Security, appointed by the Secretary of Homeland Security; and

(5) the Animal Health Institute.

SEC. 2704. DUTIES.

(a) STUDY.—

(1) IN GENERAL.—The Working Group shall conduct a study of all matters relating to developing countermeasures against agroterrorism in the United States.

(2) MATTERS TO BE STUDIED.—The matters to be studied by the Working Group shall include—

(A) the nature of United States preparedness for agroterrorism threats to crops and livestock in the United States, including an evaluation of the progress of ongoing research, studies, and programs;

(B) the availability of countermeasures against agroterrorism threats;

(C) the strategy used to develop such qualified countermeasures to both prevent and control an agroterrorism threat;

(D) the appropriateness of adapting the incentives established by the amendments made by the Project BioShield Act of 2004 (118 Stat. 835) and by this Act (including amendments made by this Act), to such countermeasures against agroterrorism;

(E) whether technological innovation is required to complete the identification, border security, and transit surveillance of livestock;

(F) the appropriateness of entering into bilateral agreements with countries in which exotic animal disease vaccines that are approved by the Department of Agriculture are produced in order to provide for the use of the vaccines by the United States in the case of an emergency;

(G) the feasibility of producing certain vaccines, especially vaccines for foot and mouth disease, in the continental United States;

(H) the feasibility of leasing Plum Island, New York, for use as a commercial vaccine production facility; and

(I) the provision of funds for the Agency for International Development to establish an office of animal and plant health, the mission of which is to assist countries in controlling and eradicating diseases that pose a threat to agriculture in the United States.

(b) RECOMMENDATIONS.—The Working Group shall develop recommendations on—

(1) specific requirements needed to accelerate the development of countermeasures against agroterrorism, including research tools, biologics, and therapeutics; and

(2) if the Working Group determines that the commercial agricultural industry is incapable or has inadequate resources to fulfill the biosecurity needs of the United States, adapting the incentives described in subparagraph (D) of subsection (a)(2).

(c) REPORT.—Not later than 1 year after the date of enactment of this Act, the Working Group shall submit to the appropriate committees of Congress a report that contains—

(1) a detailed statement of the findings and conclusions of the Working Group; and

(2) the recommendations of the Working Group for such legislation and administrative actions as the Working Group considers appropriate.

SEC. 2705. STATE AND LOCAL ASSISTANCE.

(a) STUDY.—

(1) IN GENERAL.—In consultation with the steering committee of the National Animal Health Emergency Management System and other stakeholders, the Secretary shall conduct a study to—

(A) determine the best use of epidemiologists, animal and plant pathologists, computer modelers, and statisticians as members of emergency response task forces that handle foreign or emerging agricultural disease emergencies; and

(B) identify the types of data that are necessary for proper modeling and analysis of agricultural disease emergencies.

(2) REPORT.—Not later than 180 days after the date of enactment of this Act, the Secretary shall submit a report that describes the results of the study under paragraph (1) to—

(A) the Secretary of Homeland Security; and

(B) the head of any other agency involved in response planning for agricultural disease emergencies.

(b) GEOGRAPHIC INFORMATION SYSTEM GRANTS.—

(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Interior, shall establish a program under which the Secretary shall provide grants to States and local governments to develop capabilities to use a geographic information system or statistical model for an epidemiological assessment in the event of an agricultural disease emergency.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this subsection.

(c) GRANTS TO FACILITATE PARTICIPATION OF STATE AND LOCAL ANIMAL AND PLANT HEALTHCARE OFFICIALS.—

(1) IN GENERAL.—The Secretary of Homeland Security, in coordination with the Secretary, shall establish a program under which the Secretary of Homeland Security shall provide grants to communities to facilitate the participation of State and

local animal and plant healthcare officials in community emergency planning efforts.

(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this subsection.

(d) BIOSECURITY AWARENESS AND PROGRAMS.—

(1) IN GENERAL.—The Secretary shall implement a public awareness campaign for farmers, ranchers, and other agricultural producers that emphasizes—

(A) the need for heightened biosecurity on farms; and

(B) reporting to the Department of Agriculture any agricultural disease anomaly.

(2) ON-FARM BIOSECURITY.—

(A) IN GENERAL.—Not later than 240 days after the date of enactment of this Act, the Secretary, in consultation with associations of agricultural producers and taking into consideration research conducted under the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3101 et seq.), shall—

(i) develop guidelines—

(I) to improve monitoring of vehicles and materials entering or leaving farm or ranch operations; and

(II) to control human traffic entering or leaving farm or ranch operations; and

(ii) distribute the guidelines developed under clause (i) to agricultural producers through agricultural informational seminars and biosecurity training sessions.

(B) AUTHORIZATION OF APPROPRIATIONS.—

(i) IN GENERAL.—There are authorized to be appropriated such sums as may be necessary to carry out this paragraph.

(ii) INFORMATION PROGRAM.—Of the amounts made available under clause (i), the Secretary may use such sums as are necessary to establish in each State an information program to distribute the biosecurity guidelines developed under subparagraph (A)(i).

(3) BIOSECURITY GRANT PILOT PROGRAM.—

(A) INCENTIVES.—

(i) IN GENERAL.—Not later than 240 days after the date of enactment of this Act, the Secretary shall develop a pilot program to provide incentives, in the form of grants or low-interest loans, to agricultural producers to restructure farm and ranch operations (based on the biosecurity guidelines developed under paragraph (2)(A)(i)) to achieve the goals described in clause (ii).

(ii) GOALS.—The goals referred to in clause (i) are—

(I) to control access to farms and ranches by persons intending to commit agroterrorist acts;

(II) to prevent the introduction and spread of agricultural diseases; and

(III) to take other measures to ensure biosecurity.

(iii) LIMITATION.—The amount of a grant or low-interest loan provided under this paragraph shall not exceed $10,000.

(B) REPORT.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to Congress a report that—

(i) describes the implementation of the pilot program; and

(ii) makes recommendations for expanding the pilot program.

(C) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this paragraph.

SEC. 2706. INTERAGENCY COORDINATION.

(a) AGRICULTURAL DISEASE LIAISONS.—

(1) AGRICULTURAL DISEASE MANAGEMENT LIAISON.—The Secretary of Homeland Security shall establish a senior level position within the Federal Emergency Management Agency the primary responsibility of which is to serve as a liaison for agricultural disease management between—

(A) the Department of Homeland Security; and

(B)(i) the Federal Emergency Management Agency;

(ii) the Department of Agriculture;

(iii) other Federal agencies responsible for a response to an emergency relating to an agriculture disease;

(iv) the emergency management community;

(v) State emergency and agricultural officials;

(vi) tribal governments; and

(vii) industries affected by agricultural disease.

(2) ANIMAL HEALTH CARE LIAISON.—The Secretary of Health and Human Services shall establish within the Department of Health and Human Services a senior level position the primary responsibility of which is to serve as a liaison between—

(A) the Department of Health and Human Services; and

(B)(i) the Department of Agriculture;

(ii) the animal health community;

(iii) the emergency management community;

(iv) tribal governments; and

(v) industries affected by agricultural disease.

(b) TRANSPORTATION.—

(1) IN GENERAL.—The Secretary of Transportation, in consultation with the Secretary and the Secretary of Homeland Security, shall—

(A) publish in the Federal Register proposed guidelines for restrictions on interstate transportation of an agricultural commodity or product in response to an agricultural disease;

(B) provide for a comment period of not less than 90 days for the proposed guidelines; and

(C) establish final guidelines, taking into consideration any comment received under subparagraph (B); and

(2) provide the guidelines described in paragraph (1) to officers and employees of—

(A) the Department of Agriculture;

(B) the Department of Transportation; and

(C) the Department of Homeland Security.

SEC. 2707. REGIONAL, STATE, AND LOCAL PREPAREDNESS.

(a) ENVIRONMENTAL PROTECTION AGENCY.—The Administrator of the Environmental Protection Agency, in consultation with the Secretary, shall cooperate with regional, State, and local disaster preparedness officials to include consideration of the potential environmental ef-

fects of a response activity in planning a response to an agricultural disease.

(b) DEPARTMENT OF AGRICULTURE.—The Secretary, in consultation with the Secretary of Homeland Security, shall—

(1) develop and implement procedures to provide information to, and share information among, Federal, regional, State, tribal, and local officials regarding agricultural threats, risks, and vulnerabilities; and

(2) cooperate with State agricultural officials, State and local emergency managers, representatives from State land grant colleges and research universities, agricultural producers, and agricultural trade associations to establish local response plans for agricultural diseases.

(c) FEDERAL EMERGENCY MANAGEMENT AGENCY.—The Director of the Federal Emergency Management Agency, in consultation with the Secretary, shall—

(1) establish a task force consisting of agricultural producers and State and local emergency response officials to identify the best practices for regional and State agricultural disease programs;

(2) distribute to States, tribal governments, and localities a report that describes the best practices identified under paragraph (1); and

(3) design packages containing exercises for training, based on the identified best practices, in the form of printed materials and electronic media, for distribution to State and local emergency managers, State agricultural officials, and tribal government officials.

SEC. 2708. INTERNATIONAL ACTIVITIES.

(a) INTERNATIONAL AGRICULTURAL DISEASE SURVEILLANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary, in consultation with the Secretary of State and the Administrator of the Agency for International Development, shall submit to Congress a report that describes measures taken by the Secretary to—

(1) streamline the process of notification by the Secretary to Federal agencies in the event of an agricultural disease in a foreign country; and

(2) cooperate with representatives of foreign countries, international organizations, and industry to develop and implement methods of sharing information relating to international agricultural diseases and unusual agricultural activities.

(b) INSPECTIONS OF IMPORTED AGRICULTURAL PRODUCTS.—The Secretary of Homeland Security shall—

(1) cooperate with the Secretary and any appropriate Federal intelligence official to improve the ability of the Department of Agriculture to identify agricultural commodities and products, livestock, and other goods imported from suspect locations that are recognized by the intelligence community as—

(A) having experienced an agricultural terrorist activity or an unusual agricultural disease; or

(B) harboring or having harbored an agroterrorist; and

(2) use the information described in paragraph (1) to establish priorities for inspecting imported agricultural products.

(c) BILATERAL MUTUAL ASSISTANCE AGREEMENTS.—The Secretary of State, in coordination with the Secretary and the Secretary of Homeland Security, shall—

(1) enter into mutual assistance agreements with other countries to provide and receive assistance in the event of an agricultural disease, including—

(A) training for veterinarians and agriculture specialists of the United States in the identification, diagnosis, and control of foreign agricultural diseases;

(B) providing resources and personnel to a foreign government with limited resources to respond to an agricultural disease; and

(C) bilateral training programs and exercises relating to assistance provided under this paragraph; and

(2) provide funding for a program or exercise described in paragraph (1)(C).

SEC. 2709. REVIEW OF LEGAL AUTHORITY.

(a) IN GENERAL.—The Attorney General, in consultation with the Secretary, shall conduct a review of State and local laws relating to agroterrorism and biosecurity to determine—

(1) the extent to which the laws facilitate or impede the implementation of a current or proposed response plan relating to an agricultural disease;

(2) whether an injunction issued by a State court could—

(A) delay the implementation of a Federal response plan described in paragraph (1); or

(B) affect the extent to which an agricultural disease spreads; and

(3) the types and extent of legal evidence that may be required by a State court before a response plan described in paragraph (1) may be implemented.

(b) REPORT.—Not later than 180 days after the date of enactment of this Act, the Attorney General shall submit to Congress a report that describes the results of the review under subsection (a) (including any recommendations of the Attorney General).

TITLE XXVIII—GLOBAL DISTRIBUTION OF MEDICAL COUNTERMEASURES

SEC. 2801. FINDINGS.

Congress finds the following:

(1) Experience with infections diseases like HIV and malaria in developing countries illustrate that the United States must work with developing countries to plan for the delivery of products developed under this Act (and the amendments made by this Act).

(2) For patients to benefit from these new medical interventions, there must be health care pro-

viders to prescribe and administer such interventions and assistance to purchase the treatments.

(3) The United States Agency for International Development (referred to in this title as ''USAID'') should work with its counterparts in other highly industrialized nations to gain assistance in supplying such products. The Department of Health and Human Services and USAID should undertake preapproval planning and multilateral consensus building to assure optimal outcomes for use of such products.

SEC. 2802. REPORT BY USAID.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Administrator of the United States Agency for International Development (referred to in this section as the ''Administrator of USAID''), in consultation with the entities described under subsection (b), shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives the report described under subsection (c).

(b) CONSULTING ENTITIES.—In preparing the report under subsection (a), the Administrator of USAID shall consult with the following entities:

(1) The Secretary of State.

(2) The United States Global AIDS Coordinator and Office of International Health Affairs.

(3) The Director of the Centers for Disease Control and Prevention.

(4) The Commissioner of Food and Drugs.

(5) The Surgeon General.

(6) The Secretary of Homeland Security.

(7) The Secretary of Defense.

(8) The Director of the United States Peace Corps.

(9) The World Health Organization.

(10) The United Nations Children's Fund (UNICEF).

(11) The United Nations Human Commissioner for Refugees (UNHCR).

(12) The Global Fund to fight HIV/AIDS, TB and Malaria.

(13) The Global Alliance for Vaccines and Immunizations (GAVI).

(14) The International Committee of the Red Cross, the International Federation of Red Cross and Red Crescent Societies, and the American Red Cross.

(15) Other non-profit non-government organizations and foundations with expertise in the distribution of infectious disease countermeasures.

(c) REPORT.—

(1) IN GENERAL.—The report under subsection (a) shall address—

(A) the global distribution of countermeasures procured under the Project BioShield Act of 2004 (Public Law 108–276) and this Act (and the amendments made by such Acts), particularly countermeasures to infectious diseases that are not terror weapons and that have a substantial incidence in developing countries;

(B) the existing infrastructure with respect to ensuring global distribution of such countermeasures; and

(C) plans for strengthening the infrastructure described under subparagraph (B) to ensure the effective global distribution of such countermeasures.

(2) CONTENT OF REPORT.—The report under subsection (a) shall include an analysis with respect to—

(A) the procedures by which the appropriate officials at the Office of Public Health

Countermeasure Development of the Department of Health and Human Services will notify USAID and other agencies of the types, characteristics, quantity, and timing of the countermeasures that may become available under the Project BioShield Act of 2004 (Public Law 108–276) and this Act (and the amendments made by such Acts);

(B) the types and sources of data upon which the Government will rely in determining the numbers and locations of specific populations that might benefit from such countermeasures;

(C) the means for ensuring that such countermeasures will be distributed in developing countries that cannot purchase the countermeasures;

(D) the trade and regulatory barriers to the global distribution of such countermeasures and recommendations for removing such barriers;

(E) the appropriate—

(i) priorities for national and regional distribution of such countermeasures based

on public health, medical, and other criteria;

(ii) terms for the transfer and sale of such countermeasures by the United States and other entities participating in a procurement pool established under section 319F–3 of the Public Health Service Act (as added by section 202) to other governments or nongovernment organizations and individuals;

(iii) labels and information provided to public health officials and individuals regarding such countermeasures;

(iv) protocols for licensing of countermeasures distributed globally, and policies for distribution of unlicensed investigational countermeasures;

(v) protocols for assessing the safety and effectiveness of such countermeasures and any contraindications for the utilization of such countermeasures;

(vi) pre- and post-licensing clinical testing of such countermeasures;

(vii) strategy for minimizing the development of natural resistance to such countermeasures;

(viii) liability and indemnification policies associated with global distribution of countermeasures; and

(ix) protections for intellectual property associated with such countermeasures; and

(F) the appropriate protocols for ongoing assessment of the effectiveness of the global distribution strategy, including independent assessments.

(d) ASSESSMENT BY THE DIRECTOR OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Director of the Centers for Disease Control and Prevention shall submit as part of the report under subsection (a), an assessment of—

(1) the existing public health infrastructure available to participate in the global distribution of the countermeasures described under subsection (c)(1) and the appropriate strategy for strengthening the public health infrastructure necessary for the global distribution of such countermeasures;

(2) the capacity of international public health agencies to respond to a pandemic or other public health emergency, including distribution of such countermeasures and other medical countermeasures and recommendations for strengthening such capacity;

(3) the existing information reporting and diagnostic and detection systems regarding global infectious disease and recommendations for strengthening such systems;

(4) the capacity of international public health agencies to establish and maintain quarantines or other isolation strategies to contain outbreaks of infectious diseases and recommendations for strengthening such capacity;

(5) the long-term impact on health and chronic disease of distributing such countermeasures;

(6) the ability of the United States to provide long-term medical and supportive care for victims of an infectious disease, or adverse effects of a countermeasures;

(7) the feasibility of creating a Strategic Global Stockpile of countermeasures; and

(8) the feasibility of initiating a global preparedness fund for a global response to outbreaks of infectious diseases.

TITLE XXIX—ENVIRONMENTAL PROTECTION AGENCY; DECONTAMINATION AND REMEDIATION

SEC. 2901. FINDINGS.

Congress finds the following:

(1) Nuclear, biological, and chemical decontamination present different challenges for homeland security. Nuclear contamination can be detected easily but can only be remediated by removal of radioactive material.

(2) Chemical contamination is relatively easy to detect, dissipates rapidly in warm weather, and inactivates under the right circumstances.

(3) Biological contamination presents the biggest challenge, in part, because very large indoor and outdoor areas may become contaminated (hundreds of square miles) and, in part, because detection methods and decontamination technologies are not optimally effective.

(4) Indoor biological decontamination can be more challenging than outdoor decontamination due

to the absence of weathering processes and environmental decay.

(5) Current indoor biological decontamination methods have emerged from ad hoc emergency responses to the Fall 2001 anthrax letter attacks.

(6) Opening one letter containing several grams of Bacillus anthracis spores in the Daschle Suite of the Hart Senate Office Building initiated a 3-month remediation and restoration effort that ultimately involved 26 Federal buildings at a cost of approximately $26,000,000.

(7) The transit of several other anthrax-laden letters through the Brentwood and Trenton United States Postal Service Processing and Distribution Centers led to an unprecedented 3 and ½ year remediation effort involving tens of thousands of environmental samples and on-site construction of specialized chlorine dioxide decontamination facilities at a total cost of more than $200,000,000.

(8) It is not practical to scale up these operations to handle 1 or more wide-area anthrax releases.

SEC. 2902. REPORT ON CAPABILITIES.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Administrator of the

Environmental Protection Agency (referred to in this section as the ''Administrator''), in consultation with the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, and other Federal agencies as determined appropriated by the Administrator, shall submit to the Committees on Health, Education, Labor, and Pensions, Armed Services, Homeland Security and Governmental Affairs, and Environment and Public Works of the Senate and the Committees on Energy and Commerce, Armed Services, Homeland Security, and Resources of the House of Representatives, a report that—

(1) describes—

(A) the state of technology for the detection and monitoring of nuclear, biological, and chemical contamination;

(B) the technologies and operational concepts for indoor and outdoor environmental remediation of such contamination;

(C) training and doctrine for decontamination;

(D) the safety and environmental consequences associated with such remediation and decontamination procedures;

(E) the financial costs and timelines associated with such procedures;

(F) the number of available decontamination companies and personnel, along with plans for augmenting such workforce in an emergency;

(G) the health and safety standards used to determine efficacy of clean up procedures, and the state of efforts to define such standards;

(H) an assessment of Federal assets to coordinate and implement decontamination responses; and

(I) the ability of the Environmental Protection Agency and other agencies to train, equip, and field a dedicated homeland defense decontamination capability; and

(2) makes recommendations with respect to—

(A) defining different contamination events and scenarios;

(B) research, technologies, and technology infrastructure, needed to fill technology deficiencies;

(C) development of doctrine, training, and certification methods for decontamination;

(D) methods of enhancing the Federal, as well as industrial, response capability;

(E) dual use technologies and programs;

(F) methods for coordination among the Department of Defense, the Department of Health and Human Services, the Technology Safety Working Group of the United States Army, the Defense Advanced Research Projects Agency, and the Defense Threat Reduction Agency;

(G) development of standards for decontamination (both health and environmental); and

(H) a joint decontamination research, development, and operational program.

(b) REQUEST BY ADMINISTRATOR.—

(1) IN GENERAL.—The Administrator may request that the Secretary of Health and Human Services enter into an interagency agreement, under terms acceptable to the Secretary, in which the Environmental Protection Agency may order countermeasures under procurement contracts or procurement pools established by the Secretary.

(2) PROCESSING OF ORDERS.—The ordering of a countermeasure under an agreement under para-

graph (1) (including transfers of appropriated funds between the Environmental Protection Agency and the Department of Health and Human Services to pay for such order) may be conducted pursuant to section 1535 of title 31, United States Code, if such order is processed under the terms established—

(A) by the Secretary of Health and Human Services in the interagency agreement described under paragraph (1); and

(B) in the Project BioShield Act of 2004 and this Act (and the amendments made by such Acts) with respect to the procurement of countermeasures under sections 319F–1 and 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6a and 247d–6b) (as amended by this Act).

Calendar No. 97

109TH CONGRESS
1ST SESSION

S. 975

A BILL

To provide incentives to increase research by private sector entities to develop medical countermeasures to prevent, detect, identify, contain, and treat illnesses, including those associated with a biological, chemical, nuclear, or radiological weapons attack or an infectious disease outbreak, and for other purposes.

MAY 9, 2005

Read the second time and placed on the calendar